#### Neifeld Docket No: TACT0001

Application No. : 09/666,068 Confirmation No. 6420

Patent No. : 6,379,666 Issued April 30, 2002

Applicant : Edward L. Tobinick

Filed : 12/11/2000

TC/A.U. : 1614

Examiner : Jarvis, William R. A.

# 37 CFR §1.78 Petition for Acceptance of an Unintentionally Delayed Claim for Priority and Petition for Entry of an Amendment to the Specification in an Issued Application

This is a Petition to accept an unintentionally delayed claim of priority under 37 CFR 1.78(a)(3). The entire delay between the date the priority claim was due under paragraph 37 CFR 1.78 (a)(2)(ii) and the date of submission of this Petition was unintentional.

The fee required by 37 CFR 1.17(t) is submitted herewith.

An amendment to the specification correcting the reference to related applications is submitted herewith

A draft Certificate of Correction for U.S. 6,379,666 and the fee required by 37 CFR 1.20(a) are submitted herewith.

All of the elements required under 37 CFR 1.78(a)(3) have been presented, thus awarding a corrected priority chain in application Ser. No. 09/666,068 is proper.

#### 1. STATEMENT OF THE RELIEF REQUESTED

The applicant petitions for acceptance of an unintentionally delayed claim for priority and for entry into this issued application of an amendment to correct the benefit claim under 35 U.S.C. 8120.

The chain of priority in 09/666,068 is missing a reference to application 09/275,070. As explained below, the priority chain should refer to 09/275,070 between 09/476,643 and 09/256,388, and it should specify that 09/476,643 is a continuation-in-part of 09/275,070.

In an amendment submitted herewith, page 1 of the specification (the paragraph starting with "RELATED APPLICATIONS") is amended as follows (marked-up):

This application is a divisional of Ser. No. 09/476,643, filed Dec. 31, 1999, now U.S. Pat No. 6,177,077, which is a continuation-in-part of Serial No. 09/275,070, filed March 23,1999, now U.S. Pat No. 6,015,557, which is a continuation-in-part of application Ser. No. 09/256,388, filed on Feb. 24, 1999, now abandoned.

#### II. MATERIAL FACTS

#### A CHAIN OF APPLICATION FILINGS

- 1 On February 24, 1999, the applicant filed Serial No. 09/256,388, with an original U.S. inventor declaration.
- On September 16, 1999, applicant filed a notice of express abandonment that stated:
   "Re. S.N. 09/256,388 Applicant hereby abandons the above-identified application in favor of Appln. S.N. 09/275,070, which has been allowed by Examiner Jarvis."
- Serial No. 09/275,070 was filed on March 23, 1999, and matured into U.S. 6,015,557 on January 18, 2000. The applicant filed an original U.S. inventor declaration in 09/275,070, which specifically referred to S.N. 09/256,388.
- 4. Applicant filed Serial No. 09/476,643 on December 31, 1999, which is prior to January 18, 2000, and was therefore co-pending with S.N. 09/275,070. Applicant filed an original U.S. inventor declaration attached to the specification in 09/476,643 that did not refer to any prior applications.

- 5. Page 1 of the '643 specification, under the heading "RELATED APPLICATION" stated erroneously that "This is a continuation-in-part of Application Serial No. 09/256,388, filed on February 24, 1999." This statement is erroneous because 09/256,388 had been expressly abandoned on September 16, 1999 (before the '643 application was filed) in favor of 09/275,070 which was still pending when the '643 application was field.
- 6. On July 21, 2000, applicant filed a "new" (i.e, a second) original U.S. inventor declaration in 09/476,643 that specifically refers to 09/256,388 and to 09/275,070, thus correcting priority and preserving co-pendency throughout all applications in the chain.
- 7. Serial No. 09/476,643 matured into U.S. 6,177,077 on January 23, 2001. On page 1 of the patent specification, as amended on July 21, 2000, it states "This application is a continuation-in-part of Ser. No. 09/275,070, filed March 23,1999, now U.S. Pat No. 6,015,557, which is a continuation-in-part of application Ser. No. 09/256,388, filed on Feb. 24, 1999, now abandoned."
- 7. Applicant first filed the subject divisional (Ser. No. 09/666,068) on September 19, 2000, but later was accorded an official filing date of December 11, 2000, which however is still prior to January 23, 2001. Thus divisional 09/666,068 was co-pending with its parent application 09/476,643. The applicant filed the same inventive specification, a copy of the U.S. inventor declaration from 09/476,643, and relied upon that copy of the original inventor declaration to secure the December 11, 2000 filing date.
- 8. On 12/06/2000, applicant filed a request for Correction of Filing Receipt stating erroneously: "THIS APPLICATION IS A DIV OF 09/476,643, DATED 12/31/1999, WHICH IS A CIP OF 09/256,388, DATED 2/24/1999, ABANDONED." This statement is erroneous because 09/476,643 is actually a continuation-in-part of Ser. No. 09/275,070, and cannot be a continuation-in-part of 09/256,388, due to lack of co-pendency, as explained above.
- 9. On 11/15/2001, the Related Application statement on page 1 of subject application 09/666,068 was amended by the Examiner (as indicated by handwritten, dated initials) to add the following underlined text: "This application is a divisional of Ser. No. 09/476,643, filed Dec. 31, 1999, now U.S. Pat No. 6,177,077, which is a continuation-in-part of Application Ser. No. 09/256,388, filed on Feb. 24, 1999, now abandoned." This statement is erroneous because

- 09/476,643 is actually a continuation-in-part of Ser. No. 09/275,070, and cannot be a continuation-in-part of 09/256,388, due to lack of co-pendency, as explained above.
- 11. On 02/22/2001, an Official Filing Receipt was issued in 09/666,068 stating "THIS APPLICATION IS A DIV OF 09/476,643, 12/31/1999, PAT 6,177,077 WHICH IS A CIP OF 09/256,388, 2/24/1999, ABANDONED." This statement is erroneous because 09/476,643 is in fact a continuation-in-part of Ser. No. 09/275,070, and cannot be a continuation-in-part. 09/256,388, due to lack of co-pendency, as explained above.
- 12. So in 09/666,068, the applicant's request for Correction of Filing Receipt (12/06/2000), the Examiner's amendment to the specification (11/15/2001), and the Official Filing Receipt (03/22/2001) are all incorrect. That is because 09/476,643 is actually a continuation-in-part of Serial No. 09/275,070, while 09/275,070 is a CIP of 09/256,388.
- 13. As a result of these facts the 09/666,068 application contains an erroneous priority chain.

#### B. USPTO RECORDS SHOWING THE BENEFIT CLAIM IN 09/666.068

- 14 Exhibit 1 is a copy of the 2 page transmittal letter, and page 1 of the specification filed on 09/19/2000 in application 09/666,068. The upper left hand corner of Exhibit 1 has a USPTO date stamp showing "09/19/00" The upper right hand corner shows the USPTO application number "09/666,068."
- 15 Exhibit 1, pages 1 and 2, indicate that 09/666,068 was filed as a Rule 60 divisional incorporating the prior specification and inventor declaration. Item 8 is checked, and amends the specification before the first line to recite "division of application number 09/476,643, filed Dec. 31, 1999."
- 16. Exhibit 1 page 3 shows the original first sentence of the specification, i.e., "This is a continuation-in-part of application Serial No. 09/256,388, filed on February 24, 1999" along with the Examiner's handwritten amendment dated 11/15/2001, revising the priority claim to recite "This application is a divisional of Ser. No. 09/476.643, filed Dec. 31, 1999, now U.S. Pat No. 6,177,077, which is a continuation-in-part of Application Ser. No. 09/256,388, filed on Feb. 24, 1999, now abandoned." (marked-up)

- 17. Exhibit 2, pages 1 and 2 shows the applicant filed a copy of the original U.S. inventor declaration from 09/476,643, signed by Edward L. Tobinick, M.D. on December 29, 1999, and relied upon that copy to secure the December 11, 2000 filing date.
- Exhibit 2, page 3 shows applicant requested a correction of filing receipt, dated-stamped "12/06/2000," in stating erroneously. "THIS APPLICATION IS A DIV OF 09/476,643, DATED 12/31/1999, WHICH IS A CIP OF 09/256,388, DATED 2/24/1999, ABANDONED."
- Exhibit 3, pages 3 4 show a two page transmittal letter, date-stamped "Dec 11, 2000" filed in response to the Notice to File Missing Parts, listing "A copy of the Declaration from the parent application (U.S. Serial No. 09/476.643)".
- Exhibit 3, pages 1 is a Official Filing Receipt mailed "01/24/2001." Exhibit 3, page 2 is an Official Filing Receipt mailed "02/22/2001."
- Application 09/666,068 issued as USP 6,379,666.
- Exhibit 4 is a printout of the first two columns of USP 6,379,666.
- 23. Exhibit 4 shows that the first sentence of USP 6,379,666 recites "This application is a divisional of Ser. No. 09/476,643, filed Dec. 31, 1999, now U.S. Pat No. 6,177,077, which is a continuation-in-part of application Ser. No. 09/256,388, filed on Feb. 24, 1999, now abandoned."
- 24. The foregoing facts show that the USPTO records show that application 09/666,068 is a divisional of 09/476.643.

#### C. USPTO RECORDS SHOWING THE BENEFIT CLAIM IN 09/476,643

- 25 Exhibit 5, pages 1 and 2 shows the original inventor declaration from application 09/476,643, signed by Edward L. Tobinick, M.D., on December 29, 1999. Exhibit 5, page 3 is the first page of the PTO file history for application 09/476,643, stating in the examiner's handwriting verification that "THIS APPLN is a CIP OF 09/275,070 03/23/99 PAT 6,015,557 WHICH IS A CIP OF 09/256,388 02/24/99 ABN"
- 26. Exhibit 6, page 1 is a one page transmittal letter dated "December 31, 1999 BY EXPRESS MAIL" for a new application showing the filing of an original inventor's declaration. At the upper left is the date "12/31/99" and at the upper right is the serial number "09/476643". Exhibit 6, page 2 shows the first page of the specification, which one can see originally said

- "This is a continuation-in-part of Application Serial No. 09/256,388, filed on February 24, 1990." This sentence was crossed-out by the examiner.
- 27. Exhibit 7, page 1 is the first page of the PTO File History, amended in handwriting by the examiner to state "This Appln is a CIP OF 09/275,070 PAT #6,015,557 WHICH IS A CIP OF 09/256,388 02/24/99 ABN." Exhibit 7, page 2 is another copy of the one page transmittal letter dated "December 31, 1999 BY EXPRESS MAIL" for a new application showing the filing of an original inventor's declaration. At the upper left is the date "12/31/99" and at the upper right is the serial number "09/476643". Exhibit 7, page 3 is an inventor declaration filed with the application. Exhibit 7, page 4 shows the first page of the specification as filed, which stated "This is a continuation-in-part of Application Serial No. 09/256,388, filed on February 24, 19990". This sentence was later crossed-out by the examiner.
- Exhibit 8, page 1 is a Terminal Disclaimer over US 6,015,557, and page 2 is an original inventor declaration claiming benefit of application "09/275,070 March 23, 1999 U.S. Patent No. 6.015.557" and "09/256,388 February 24, 1999 Abandoned"
- 29 Exhibit 9, page 2 shows the handwritten amendment by the examiner, dated 8/24/2000 changing the first sentence of the specification to recite "This application is a continuation-in-part of Application Serial No. 09/275,070, filed on March 23, 1999, now U.S. Patent 6,015,557, which is a continuation-in-part of Application Ser. No. 09/256,388, filed on February 24, 1999, now abandoned"
- 30. Exhibit 10 is a printout of the first two columns of US 6,177,077, stating in the first paragraph that "This application is a continuation-in-part of Application Serial No. 09/275,070, filed on Mar 23, 1999, now U.S. Pat. No. 6,015,557, which is a continuation-in-part of Application Ser. No. 09/256,388, filed on Feb. 24, 1999, now abandoned."
- 31. The foregoing facts show that the USPTO records show that application 09/476,643 was a continuation-in-part of 09/275,070.

#### D. USPTO RECORDS SHOWING THE BENEFIT CLAIM IN 09/275.070

32. Exhibit 11, page 1 is a transmittal letter dated "March 23, 1999 BY EXPRESS MAIL."
Page 2 is the first page of the specification as filed. Pages 3 and 4 are a copy of the original inventor declaration, claiming benefit under 35 USC 120 to "09/256,388" 24 February 1999

- pending" signed on 3-20-99 by two inventors, Dr. Edward L. Tobinick, and Arthur Jerome Tobinick. Pages 5-8 are a copy of a Petition to Make Special filed March 23, 1999. At the upper right on page 5 is the serial number "09/257070" and the date "03/23/99".
- 33. Exhibit 12 is a printout of the first two columns of US 6,015,557, stating in the first paragraph that "This application is a continuation-in-part of Application Ser. No. 09/256,388, filed on Feb. 24, 1999, now abandoned "
- 34 The foregoing facts show that the USPTO records show that application 09/275,070 was a continuation-in-part of 09/256,388.

#### E USPTO RECORDS SHOWING THE FILING DATE OF 09/256.388

- 35 Exhibit 13, page 3 is a copy of the first page USPTO file history for application 09/256,388, showing "FILING DATE 02/24/99." Pages 1 2 show the original inventor declaration, dated February 21, 1999, signed by two inventors, Dr. Edward L. Tobinick, and Arthur Jerome Tobinick. In 09/256,388, inventor "Edward L. Tobinick, M.D." is the same person as "Dr. Edward L. Tobinick" in 09/275,070 (and "Edward L. Tobinick, M.D." in 09/476 643)
- 36. Exhibit 14 is another copy of the inventor declaration. Page 2 is transmittal letter dated "FEBRUARY 24, 1999 BY EXPRESS MAIL" listing the filing of an inventor declaration, and specification. Page 3 of Exhibit 14 is the first page of the specification as filed.
- 37 Exhibit 15, pages 1 2 is a Notice of Abandonment "mailed 09/27/99." Exhibit 15, page 3 is communication by applicant dated 9/16/99 stating: "Re: S.N. 09/256,388 Applicant hereby abandons the above-identified application in favor of Appln. S.N. 09/275,070, which has been allowed by Examiner Jarvis."
- 38 The foregoing show that the USPTO records show that application 09/256,388 was filed on February 24, 1999 and abandoned on Sept. 16, 1999.

#### F. FACTS WHY THE REQUESTED RELIEF IS NOT MOOT

 Pending Tobinick application 12/714,205 claims priority to 09/666,068 as "a continuation of application Serial No. 11/262,528, filed on Oct. 28, 2005, which is a division of application Ser. No. 10/269,745, filed Oct. 9, 2002, now U.S. Pat. No. 6,982,089, which is a continuation-in-part of application Ser. No. 09/841,844, filed on Apr. 25, 2001, now U.S. Pat. No. 6,537,549, which is a continuation-in-part of application Ser. No. 09/826,976, filed on Apr. 5, 2001, now U.S. Pat. No. 6,419,944, which is a continuation-in-part of application Ser. No. 09/666,068, filed Dec. 11, 2000, now U.S. Pat. No. 6,379,666, which is a division of application Ser. No. 09/476,643, filed on Dec. 31, 1999, now U.S. Pat. No. 6,177,077, which is a continuation-in-part of application Ser. No. 09/275,070, filed on Mar. 23, 1999, now U.S. Pat. No. 6,015,557, which is a continuation-in-part of application Ser. No. 09/256,388, filed on Feb. 24, 1999, now abandoned." (emphasis added)

# G. FACTS SHOWING THE FAILURE TO PROPERLY CLAIM BENEFIT WAS UNINTENTIONAL

40 The foregoing facts 1 - 39 show that failure to claim in this application priority to 09/666.068 was an unintentional clerical error.

# H. FACTS RELATING TO THE LEGAL STANDARD FOR ENTRY OF CORRECTION OF BENEFIT CLAIMS

41 Exhibit 16 is a copy of pages from Section 1481 03 of the current version of the MPEP.

#### 1. RELATED USPTO PROCEEDINGS

- The applicant is presenting herewith an Amendment to correct benefit in prior application 09/666,068.
- 43. The applicant is filing herewith a corresponding request for a certificate of correction in the patent that issued from this application, U.S. Pat. 6.379,666.

#### HE REASONS WHY THE PETITION SHOULD BE GRANTED

On the merits, the petition should be granted because (1) the relief requested is not moot; (2) an amendment as to benefit in an issued application is submitted herewith, (3) all of the elements required under 37 CFR 1.78(a)(3) have been presented, so awarding a corrected priority chain in application Ser. No. 09/666,068 is proper, and (4) a request for the appropriate Certificate of Correction has been filed.

#### A. STANDARD FOR GRANT OF PETITION

#### 1. FORMAL MATTERS

This petition requests entry of an amendment in an issued application filed after. November 29, 2000. Therefore petition under Rule 1.78 is proper.

(CX13 "Eighteen-Month Publication Questions and Answers" http://www.uspto.gov/patents/law/aipa/18month/18monthfaq.jsp#cx)

The applicant is paying the 37 CFR 1.17(t) fee therefore via credit card upon EFS web submission of this petition.

#### 2 THE PETITION IS NOT MOOT

The petition is not moot because, even though 09/666,068 is issued, a pending application claims priority to this application. Fact 39.

#### 3 CRITERIA FOR CORRECTION OF BENEFIT

The amendment that this petition requests be entered corrects benefit. The requirements to obtain benefit and to correct benefit are governed by Rule 1.78. MPEP 1481.03 contains criteria for granting a certificate of correction correcting benefit in an issued patent. See the section titled "Correction of 35 U.S.C. 119 and 35 U.S.C. 120 Benefits." In view of the foregoing, this petition shows compliance with the criteria for correction of benefit under Rule 1.78.

### B. THE APPLICANT HAS COMPLIED WITH THE CRITERIA FOR CLAIMING BENEFIT TO 09/666.068

# 1. THE APPLICANT HAS COMPLIED WITH THE REQUIREMENTS OF 37 C.F.R. 1.78

The following paragraphs in this subsection identify requirements in Rule 1.78 for claiming priority, and show compliance with those requirements.

37 CFR 1.78(a)(1) authorizes a claim to priority to prior filed applications only if the applications name at least one common inventor and disclose the claimed invention. The prior filed application is 09/666,068. The common inventor is Edward L. Tobinick, M.D. Facts 14-39.

37 CFR 1.78(a)(1)(i) and (ii) require the prior filed applications to be either international applications or applications entitled to a filing date. The prior filed applications is 09/666,068, which was entitled to and accorded a filing date. Exhibit 1, Facts 14 - 15.

37 CFR 1.78(a)(2)(i) requires a claim to priority to be present or amended to be present during the pendency of the application, unless the application was filed prior to November 29, 2000, and to state the relationship between the applications. This application is an application filed under 111(a) after November 29, 2000. Accordingly, the amendment submitted herewith provides the specific references and relationships to 09/476,643, which is a continuation-in-part of 09/275,070, which is a continuation-in-part of 09/256,388.

37 CFR 1.78(a)(2)(iii) requires the claim to priority be presented in an application data sheet or amendment to the first sentence of the specification following the title. The amendment submitted herewith provides the claim to priority to 09/666,068 in the first sentence of the specification following the title.

37 CFR 1.78(a)(3) authorizes an amendment claiming priority after the time periods specified by 1.78(a)(2)(ii) only if the late filing of the claim the priority was unintentionally delayed. The entire delay between the date the priority claim was due under paragraph 37 CFR 1.78 (a)(2)(ii) and the date of submission of this Petition was unintentional. Fact 40.

37 CFR 1.78 contains no other requirements applicable to grant of this petition. In view of the foregoing, this petition should be granted.

DATE: 3-30-2010 SIGNATURE: /RobertHahl#33,893/

PRINTED NAME: Robert W. Hahl, Ph.D.

Date/time code: March 30, 2010 (5:56pm)

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\*\*> PTO/SB/13 (11-98)

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Approved for use through 6/30/99. OMB 0881-0003
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#### QUEST FOR FILING A PATENT APPLICATION UNDER 37 CFR 1.60

REQUEST FOR FILIN	ANTICIPATED CLASSIFICATION I									3
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Address to: Assistant Co

Assistant Commissioner for Patents Washington, D.C. 20231

This is a request for filing a □continuation ☑ divisional application under 37 CFR 1.80, of panding prior Application Number 1997 416, 643. Ned on 12/31/09 writted THE INHIBITIANS. FOR THE TREATMENT OF TREATMENT OF THE WORLDETTAL ARD MUSCULAR DISORDERS

1. Enclosed is a copy of the letset Inventor-algorator for application, including a copy of the ceth or declaration showing the original signature or an indication it was signed, I hereby verify that the papers are a true copy of the lettest signed prior application number 0.97, 476, 6.63, and further that all statements made herein of my own knowledge are true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that euch willful false statements may looperatize the validity of the application or any petent issuing thereon.

CLAIMS	(1) FOR	(2) NUMBER	(2) NUMBER FILED (3)		A (4) RATE	(5) CALCULATIONS
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	<b>F</b>				TOTAL =	\$345.00

2. X A verified statement to	establish small entity	etatus under 37 CFR 1.9	and 1.27

- was filed in prior application number 09 / 476,643 and such status is still proper and desired (37 CFR 1.28(a)).
- The Commissioner is hereby authorized to charge any fees which may be required under 37 CFR 1.16 and 1.17, or credit any overpayment to Deposit Account No.

   A duplicate copy of this sheet is endosed.
- 4. A check in the amount of \$ 345 is enclosed.
- Cancel in this application original claims 1-49 + 66 99 of the prior application before calculating the filling fee. (At least one original independent claim must be retained for filing purposes.)
- 6. M The inventor(s) of the invention being daimed in this application is (are):
- 7. This application is being filed by less than \$\frac{1}{4}\$ inventors named in the prior application. In accordance with \$7 CFR 1.50(b), the Commusioner is requested to delete the name(s) of the following person or persons who are not inventors of the inventor heiro delating in this application.
- 8. Amend the specification by inserting before the first line the sentence: "This appairation is a Continuation of the specification is a Continuation of the specification of the specification is a Continuation of the specification of the s
- (3) division of application number 09/ 476,643, filed Dec. 31, 1999, (status, abandoned, pending, etc.).

[Page 1 of 2]

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Rev. 3, July 1997

DES

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[Page 2 of 2]

Assignee of complete interest. Certification under 37 CFR 3.73(b) is enclosed.

Registration number if acting under 37 CFR 1.34(a)

EZRA SUTTON Typed or printed name

25,770

Date

Attorney or agent of record Filed under 37 CFR 1.34(a)

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#### TNF INHIBITORS FOR THE TREATMENT OF NEUROLOGICAL, RETINAL AND MUSCULAR DISORDERS

RELATED APPLICATION
application's a divisional of 07/476, 643, Filed Decomber 31, 1999, now U.S. Robert 6, 177,077,

This, is a continuation-in-part of Application Serial No. 09/256,388, filed on now abandoned

February 24, 1999

### FIELD OF THE INVENTION

The present invention relates to tumor necrosis factor (TNF) antagonists or TNF blockers for the treatment of neurological disorders, trauma, injuries or compression; demyelinating neurological disorders, including multiple sclerosis; neurodegenerative diseases, including Alzheimer's disease; muscular disorders; and disorders of the optic nerve and retina (hereinafter "Neurologic and Related TNF Disorders"). More particularly, the TNF antagonists, TNF inhibitors or TNF blockers, are used for the treatment, prevention or amelioration of these "Neurologic and Related TNF Disorders" by modulating the action of TNF in the human body. The use of these TNF antagonists or TNF blockers results in the amelioration of these disorders and diseases and represents a novel use for this class of drugs.

### BACKGROUND OF THE INVENTION

Neurological disorders due to demyelinating disease (e.g. multiple sclerosis), immune disease, inflammation, trauma, or compression, occur in different clinical forms depending upon the anatomic site and the cause and natural history of the physiological problem. For example, in Alzheimer's disease the brain undergoes a serious form of neurodegeneration

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 CFR 1.2(f) AND 1.27(b) - INDEPENDENT INVENTOR

As a below-named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, Untiled States Code, to the Patent and Trademark office with regard to the invention entitled TMF INHIBITORS FOR THE TREATERING TO NEW ORDINGIAL RETURNAL AND NUMBERIAL SERVICES.

TREATMENT OF NEUROLOGICAL, RETINAL AND MUSCULAR DISORDERS
described in:
(x ) the specification filed herewith     (y ) Application Serial No
Pâtent No, issued
I have not assigned, granted, conveyed, or licensed and am under no obligation, under contract or law to assign, grant, convey, or license, any rights in the
invention to any person who could not be classified as an independent inventor
under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a

Each person, concern, or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

x j	no	such	person,	conce	n, or	organiza	ation	below*	
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nonprofit organization under 37 CFR 1.9(e).

PULT. NAME ADDRESS

Separate verified statements are required from each named person, \*NOTE: concern, or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

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I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF INVENTOR	NAME OF INVENTOR	NAME OF INVENTOR
A I were the first the second	Signature of Inventor	Signature of Inventor
December 29, 1999		
Date	Date	Date

TOBINICK

99 5:19PM:

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my

I believe I am the original, first and sole inventor (if only one name is into the party or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled TNF INHIBITORS FOR THE TREATMENT OF NEUROLOGICAL , the specification of which RETINAL AND MUSCULAR DISORDERS

(check one) EX is attached hereto

was filed on \_ Application Serial No. (if applicable). and was amended on ...

ATION FOR PATENT APPLICATION

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, \$1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, \$119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Priority Claimed Prior Foreign Application(s) (Day/Month/Year Filed) (Country) (Number) (Day/Month/Year Filed) No (Number) (Country) (Day/Month/Year Filed) No (Number) (Country)

I hereby claim the benefit under Title 35, United States Code, \$120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filling date of the prior application and the national or PCT international filing date of this application:

(Status-patented, pending, abandoned) (Application Serial No.) (Filing Date) (Status-patented, pending, abandoned) (Filing Date) (Application Serial No.)

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

Ezra Sutton, Reg. No. 25,770 (732) 634-3520 at telephone no. . Address all telephone calls to \_

Address all correspondence to EZRA SUTTON, P.A Plaza 9, 900 Route 9 Woodbridge, New Jersey 07095

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor Edward L. TOBINICK, M.D. Inventor's signature Company Comp Date December 29, 1999 United States of America Citizenship \_ 100 UCLA Medical Plaza, Suite 205 Post Office Address . Los Angeles, California 90024-6903 Full name of second joint inventor, if any Date .... Second Inventor's signature \_ Citizenship \_\_ Residence ... Post Office Address ..

Dec\_8-00 11:06AM;

TOBINICK 3.0-009 (CIP) (DIV I)

IN THE UNITED STATES PATENT AND TRADEMARK OFF OR PATENT AND TRANSPORTED TO THE PARTY OF THE P

In re patent application of: EDWARD L. TOBINICK, M.D.

Serial No. 09/666,068

Group Art Unit 1614

Filed: September 19, 2000

Examiner

FOT: THE INHIBITORS FOR THE TREATMENT OF NEUROLOGICAL. RETINAL AND MUSCULAR DISORDERS

December 6, 2000

Assistant Commissioner for Patents Washington, D.C. 20231

# CORRECTION OF FILING RECEIPT

sir:

Please issue a corrected filing receipt, and correct the following data:

THIS APPLICATION IS A DIV OF 09/476,643, DATED 12/31/1999,

WHICH IS A CIP OF 09/256,388, DATED 2/24/1999, ABANDONED.

See the enclosed filing receipt.

Respectfully submitted,

EZRA SUTTON, P.A.

Reg. No. 25,770

Plaza 9, 900 Route 9 Woodbridge, New Jersey 07095 (732) 634-3520 ES/jmt



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Ezra Sutton PA Plaza 9 900 Route 9 Woodbridge, NJ 07095 OIP

Date Mailed: 11/15/2000

Receipt is acknowledged of this neuprovisional Paient Application. It will be considered in its order and you will. On the notified as to the usuals of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICATION and TITLE OF INVENTION when inquiring about this application. Fees DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this recipilation. In order of the property of the property of the data presented on this recipilation of Customer Service Center, Please provide a copy of this Plang Receipt with the changes recipilated the control of the property of the control of the property of the control of the property of appropriate).

Applicant(s)

Edward L. Tobinick, Los Angeles, CA;

Continuing Data as Claimed by Applicant

THIS APPLICATION IS A CIP OF 09/256,388 02/24/1999 ABN

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Foreign Applications

If Required, Foreign Filing License Granted 11/15/2000

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\*\* SMALL ENTITY \*\*

Title

TNF inhibitors for the treatment of neuological, retinal and muscular disorders

Preliminary Class

514

Data entry by : HINES, BRENDA

Team : OIPE

Date: 11/15/2000







UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES FEBRUARY AND THE TRANSPORT

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## United States Patent and Trademark Office

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 2020

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EZRA SUTTON, P.A. Plaza 9, 900 Route 9 Woodbridge, NJ 07095 CORRECTED FILING RECEIPT

\*OC000000005701748\*

Date Mailed: 01/24/2001

Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE. NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt, if an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Customer Service Center. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the PTO processes the reply to the Notice, the PTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

#### Applicant(s)

Edward L. Tobinick, Los Angeles, CA:

#### Continuing Data as Claimed by Applicant

THIS APPLICATION IS A DIV OF 09/476,643 12/31/1999 PAT 6,177,077 WHICH IS A CIP OF 09/256,388 02/24/1999 ABN

#### Foreign Applications

If Required, Foreign Filing License Granted 11/02/2000

" SMALL ENTITY "

Title

TNF inhibitors for the treatment of neurological, retinal and muscular disorders

Preliminary Class

514

Data entry by : BURSE, JANICE

Team : OIPE

Date: 01/24/2001



### INITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS UNITED STATES PATENT AND TRADEMARK OFFICE WASHINGTON D.C 2C221 WWW LINDSO GOV

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EZRA SUTTON, P.A. Plaza 9, 900 Route 9

Woodbridge, NJ 07095

12/11/2000

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CONFIRMATION NO. 6420

**FILING RECEIPT** 

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Date Mailed: 02/22/2001

Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Customer Service Center. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the PTO processes the reply to the Notice, the PTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

Edward L. Tobinick, Los Angeles, CA;

Continuing Data as Claimed by Applicant

THIS APPLICATION IS A DIV OF 09/476,643 12/31/1999 PAT 6,177,077 WHICH IS A CIP OF 09/256,388 02/24/1999 ABN

Foreign Applications

If Required, Foreign Filing License Granted 11/02/2000

Projected Publication Date: 05/31/2001

Non-Publication Request: No

Early Publication Request: No

" SMALL ENTITY "

Title

TNF inhibitors for the treatment of neurological, retinal and muscular disorders

Sector # \$3

TOBINICK 3.0-009 (CIP) (DIV II)

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of: EDWARD L. TOBINICK, M.D.

Serial No. 09/666,068

Group Art Unit 1614

Filed: September 19, 2000

Examiner

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December 6, 2000

For: TNF INHIBITORS FOR THE TREATMENT OF NEUROLOGICAL,

RETINAL AND MUSCULAR DISORDERS

Assistant Commissioner for Patents Washington, D.C. 20231

Attention: Customer Service Center
Tnitial Patent Examination Division

#### RESPONSE

Sir:

This is in response to the "Notice to File Missing Parts of Nonprovisional Application," dated November 2, 2000.

Enclosed for filing are the following:

- 1. Page 54, which was missing from the application;
- 2. A copy of the Declaration from the parent application (U.S. Serial No. 09/476,643);
- 3. A copy of the Verified Statement for a Small Entity from the parent application (U.S. Serial No. 09/476,643);
  - 4. The surcharge fee of \$65 for a small entity; and
- 5. A copy of the Notice to File Missing Parts of Nonprovisional Application.

It is requested that this application be given a new filing date upon receipt of this Response.

Respectfully submitted,

EZRA SUTTON, P.A.

EZRA SUTTON, Reg. No. 25,770

Plaza 9, 900 Route 9 Woodbridge, New Jersey 07095

(732) 634-3520

ES/jmt

Enclosures

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST-CLASS MAIL IN AN ENVELOPE ADDRESSED TO: ASSISTANT COMMISSIONER FOR PATENTS WASHINGTON, D.C. 20231 ON

Data Decar Last & 2000

By Judita M. Graina

#### THE INHIBITORS FOR THE TREATMENT OF NEUROLOGICAL, RETINAL AND MUSCULAR DISORDERS

#### RELATED APPLICATION

This application is a divisional of Ser. No. 09/476,643, filed Dec. 31, 1999, now U.S. Pat No. 6,177,077, which is a continuation-in-part of application Scr. No. 09/256,388, filed on Feb. 24, 1999, now abandoned.

#### FIELD OF THE INVENTION

The present invention relates to tumor necrosis factor (TNF) antagonists or TNF blockers for the treatment of neurological disorders, trauma, injuries or compression; 15 demyelinating neurological disorders, including multiple selerosis; neurodegenerative diseases, including Alzheimer's disease; muscular disorders; and disorders of the optic nerve and retina (hereinafter "Neurologic and Related TNF Disorders") More particularly, the TNF antagonists, 27 TNF inhibitors or TNF blockers, are used for the treatment, prevention or amelioration of these "Neurologic and Related I'NI' Disorders" by modulating the action of TNP in the human body. The use of these TNF antagonists of TNF blockers results in the amelioration of these disorders and 25 diseases and represents a novel use for this class of drugs.

#### BACKGROUND OF THE INVENTION

Nenmlogical disorders due to demyelinating disease (e.g. a. multiple sclerosis), immune disease, inflammation, trauma, or compression, occur in different clinical forms depending upon the anatomic site and the cause and natural history of the physiological problem. For example, in Alzheimer's disease the brain undergoes a serious form of neurodogeneration of mkn-nyn etiology. Common to all of these disorders is the fact that they can cause permanent neurological damage, that damage can occur rapidly and be irreversible, and that current treatment of these conditions is unsatisfactory, often requiring surgery and/or the use of pharmaeologic agents, which are often not completely suc-

These neurological conditions include acute spinal cord trauma, spinal cord compression, spinal cord hematoma, cord confusion (these cases are usually traumatic, such as as to this task because they have been demonstrated to dramotorcycle accidents or sports injuries); nerve compression, the most common condition being a herniated disc causing sciatic purve compression, acumpathy, and pain; but also including cervical disc hemiation, causing nerve compression in the neck; seute or chronic spinal and compression from cancer (this is usually due to metastases to the spine, such as from prostate, breast or lung cancer); autommune disease of the nervous system; and demyelinating diseases, the most common condition being multiple sclerosis.

of the aforementioned neurological problems and conditions are particularly hazardous because they are used either at high dosage, with a corresponding increasing risk of side effects, or because they are used chronically, also increasing their adverse effects. Lastly, steroids are only partially as effective or completely ineffective

Tionor necrosis factor (TNF), a naturally occurring cytokine, plays a central role in the inflammatory response and in ammune injury. TNF is formed by the cleavage of a precursor transmembrane protein, forming soluble mol- is ecules which aggregate to form trimolecular complexes. These complexes then bind to recepsors found on a variety

of cells. Binding produces an array of pro-inflammatory effects, including release of other pro-inflammatory evtokines, including interleukin (IL)-6, IL-8, and IL-1; release of marrix metalloproteinases; and up regulation of the expression of endothelial adhesion molecules, further amplifying the inflammatory and immune cascade by attracting lenkocytes into extravascular tissues. TNF is now well established as key in the pathogenesis of rheumatoid arthritis (RA) and Crobn's Disease.

Specific inhibitors of TNF, only recently commercially available, now provide the possibility of therapeutic intervention in TNF mediated diseases. Dramatic therapeutic success has already been demonstrated with infliximab, a chimerie anti-TNF monockonal antibody (mAb), in treating Crohu's Disease and RA; and with etanercept, a recombinant fusion protein consisting of two soluble TNF receptors ioined by the Fe fragment of a human leG1 molecule, in treating RA and Psociatic Arthritis. Other specific anti-TNF agests are under development, including D2E7 (a human anti-TNF mAb), CDP 571 (a chimeric, but 95% humanized, anti-TNF mAb), and a pocylated soluble TNF type 1 receptor. Additionally, thalidomide has been demonstrated to be a potent anti-TNP agent. Further, anti-TNF therapies may include gone therapy and the development of selective intribitors of the TNF-aloha converting enzyme.

As with other organ systems. TNF has been shown to have a key role in the central pervous system. There is a need for TNF inhibitors that will open a new reatm of therapeutic possibilities for a wide variety of neurological and related disorders. These disorders are diverse and include inflammatory and autoimmune disorders of the nervous system, including multiple sclerosis, Guillain Barre syndrome, and myasthenia gravis; degenerative disorders of the nervous system, including Aizheimer's disease, Parkinson's disease and Huntington's disease, disorders of related systems of the retina and of muscle, including optic neuritis, macular degeneration, diabetic retinopathy, dermatomyositis, snayotrophic lateral sclerosis, and muscular dystrophy; and injuries to the nervous system, including tranmatic brain injury. acmie spinal cord injury, and siroke.

The limited ability of the body to effect repair after injury to the nervous system, the devastating nature of these diseases and the lack of effective therapy all highlight the importance of early therapy simed at preventing or limiting neuronal destruction. Anti-TNF therapies are ideally suited matically limit inflammation by interrupting the inflammatory cascade at a fundamental level.

There remains a need for a new pharmacologic treatment of these aforementioned physiological problems of the neryous system associated with amountaine disease, demyelinating diseases, neurodegenerative diseases, trauma, injuries and compression with the pharmacological use of TNP antagonists or TNF blockers, which are greatly beneficial for the large number of patients whom these conditions affect. Steroid drugs such as corrisone that are used to treat many 33. Drugs, which are powerful TNF blockers are etanercept, infliximab, pegylated soluble TNF Receptor Type I (PECs TNF-R1), other agents containing soluble TNF receptors, CDP571 (a humanized monoclonal anti-TNF-alpha antibodies), thalidomide, phosphodiesterase 4 (IV) inhibitor thalidomide analogues and other phosphodiesterase IV inhibitors. Etanercept or infliximab may be used for the immediate, short term and long term (acute and chronic) blockade of TNF in order to minimize neurological damage mediated by TNF dependent processes occurring in the aforementioned neurological disorders. The use of these PNF antagomists or TNF blockers would result in the amehoration of these physiological neurological problems.

# ECLARATION FOR PATENT APPLICATION

Docket No. TOBINICK

As a below named inventor, I hereby declare that:

Exhibit S\_Pages170-172fromiFW\_69476543\_077.pdf

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My residence, post office addre	ess and citizens	hip are a	as stated	below next to	my name.			
I believe I am the original, first names are listed below) of th TNF INHIBITORS FO	e subject matt	er which	is clai	med and for	which a nati	ent is somehe	on the inventi	on entitled
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Prior Foreign Application(s)							Priority	Claimed
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I hereby appoint the following Trademark Office connected U	attorney(s) and	or agent	ı(s) to pi	osecute this ap	oplication and	to transact a	ll business in the	Patent and
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Applicant or Patentee: Edward L. TOBINICK, M.D. Serial or Patent No.: Filed or Issued:	Attorney's Docket No.:
Title: THE INHIBITORS FOR THE TREATMENT OF NEUROLOGIC	AL,
RETINAL AND MUSCULAR DISORDERS	mum where
VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL STATUS (37 CFR 1.2(f) AND 1.27(b) - INDEPENDENT 1	ENTITY INVENTOR
As a below-named inventor, I hereby declare that I qualify inventor as defined in 37 CFR 1.9(c) for purposes of paying Section 41(a) and (b) of Title 35, United States Code Trademark office with regard to the invention en	reduced fees under
described in:  M   the specification filed herewith [	
I have not assigned, granted, conveyed, or licensed and am ut under contract or law to assign, grant, convey, or license, invention to any person who could not be classified as an ir under 37 CFR 1.9(c) if that person had made the invention, which would not qualify as a small business concern under nonprofit organization under 37 CFR 1.9(e).	any rights in the
Each person, concern, or organization to which I have conveyed, or licensed or am under an obligation under contrac grant, convey, or license any rights in the invention is list	assigned, granted, t or law to assign, sted below:
{ % } no such person, concern, or organization { } persons, concerns, or organizations listed below*	
*NOTE: Separate verified statements are required from concern, or organization having rights to the to their status as small entities. (37 CFR 1.	each named person, invention averring 27)
FULL NAME	
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FULL NAME ADDRESS [ ] INDIVIDUAL [ ] SMALL BUSINESS CONCERN [ ] NON	PROFIT ORGANIZATION
FULL NAME	
ADDRESS [ ] INDIVIDUAL [ ] SMALL BUSINESS CONCERN [ ] NON:	PROFIT ORGANIZATION
I acknowledge the duty to file, in this application or pater any change in status resulting in loss of entitlement to a prior to paying, or at the time of paying, the earliest of t maintenance fee due after the date on which status as a small appropriate. (37 CFR 1.28(b))	
I hereby declare that all statements made herein of my own knc that all statements made on information and belief are belie further that these statements were made with the knowledge statements and the like so made are punishable by fine or impunder Section 1001 of Title 18 of the United States Code, an false statements may jeopardize the validity of the appliassing thereon, or any patent to which this verified states	that willful false
Edward L. TOBINICK, M.D.	
NAME OF INVENTOR NAME OF X	INVENTOR e of Inventor
Signature of Inventor Signature of Inventor Signatur	

December 29, 199

Date Date Date

SERIAL NUMBER		FILING DATE	CLASS	GRO	OUP ART UNIT	ATTORNEY DO	CKET NO.
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Exhibit 6 Pages112-114fromIFW 09476643 077.pdf

LAW OFFICES

### EZRA SUTTON, P. A.

A PROFESSIONAL CORPORATION 900 ROUTE 9

WOODBRIDGE, NEW JERSEY 07095

December 31, 1999

BY EXPRESS MAIL



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\$1,416

TRADEMARKS COPYRIGHTS

(732) 634-3520 CABLE: TRADEPAT FAX: (732) 634-3511

Assistant Commissioner for Patents Washington, D.C. 20231

File No.:

Dear Sir:

\*MEMBER OF NJ. AND N.Y. BARS

EZRA SUTTON\*

OF COUNSEL ROBERT A. GREEN

DAVID L. DAVIS

TOBINICK 3.0-009 (CIP)

Inventor(s): Edward L. TOBINICK

TOTAL filing and assignment recording fees

\_\_\_\_ for

THFIINHIBITORS FOR THE TREATMENT OF NEUROLOGICAL. RETINAL AND MUSCULAR DISORDERS

PETITION TO MAKE SPECIAL

\_\_\_\_Will follow

Appln. No.\_\_\_\_\_

Assignee: None

Enclosed herewith are the following documents in the aboveidentified application for a Letters Patent of the United States:

	Pages of Abstract ~ Veri	ried Statement for Small Entity Status
×	29 Pages of Abstract	ion, Power of Attorney & Petition
X	99 Number of Claims Two (2)	return-addressed postcards
į,	₩Sheets of Drawings (PLEASE	ton, Power or Attorney & Petition return-addressed postcards PROVIDE FILING DATE & SERIAL NUMBER) d to copy of this letter) F PRIOR ART CITED BY APPLICANT; & PRIOR
-10	Assignment for Recording (attache	d to copy of this letter)
ď,	A PETĪTION TO MAKE SPECIĀL; LIST O	F PRIOR ART CITED BY APPLICANT; 3 PRIOR
3	5 PRIOR ART PATENTS: FER OF S	1 30
	Check No. $3889$ in the amount of \$51 (\$380)	) calculated as follows:
	Basic Fee (**Large Business \$760.00)	
	Additional Fees:	
	Total number of claims 99	·
	Total number of claims in excess	of 20, 79 times (**\$18)(*\$9)711
	Number of independent claims 8	
	Number of independent claims min	us 3, 5 times (**\$78)(*\$39) / 1.95
	Assignment recording fee (\$40)	
	Multiple dependent claims (**\$26	0) (*\$130) \$1,286

\_\_\_\_Enclosed Respectfully submitted,

EZRA SÚTTON, Reg No. 25,770

ES/imt Enclosures

is claimed.

CONVENTION DATE

Priority Document:

TOBINICK 3.0-009 (CIP)

# TNF INHIBITORS FOR THE TREATMENT OF NEUROLOGICAL, RETINAL AND MUSCULAR DISORDERS

#### RELATED APPLICATION

This is a continuation-in-part of Application Serial No. 09/256,388, filed on

bruary 24, 1999.

### FIELD OF THE INVENTION

The present invention relates to tumor necrosis factor (TNF) antagonists or TNF blockers for the treatment of neurological disorders, trauma, injuries or compression; demyelinating neurological disorders, including multiple sclerosis; neurodegenerative diseases, including Alzheimer's disease; muscular disorders; and disorders of the optic nerve and retina (hereinafter "Neurologic and Related TNF Disorders"). More particularly, the TNF antagonists, TNF inhibitors or TNF blockers, are used for the treatment, prevention or amelioration of these "Neurologic and Related TNF Disorders" by modulating the action of TNF in the human body. The use of these TNF antagonists or TNF blockers results in the amelioration of these disorders and diseases and represents a novel use for this class of drugs.

#### BACKGROUND OF THE INVENTION

Neurological disorders due to demyelinating disease (e.g. multiple sclerosis), immune disease, inflammation, trauma, or compression, occur in different clinical forms depending upon the anatomic site and the cause and natural history of the physiological problem. For example, in Alzheimer's disease the brain undergoes a serious form of neurodegeneration







# UNITED STATES DEPAREMENT OF COMMERCE Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

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LAW OFFICES

### EZRA SUTTON, P. A.

A PROPESSIONAL CORPORATION PLAZAG

900 ROUTE 9

WOODBRIDGE, NEW JERSEY 07095

December 31, 1999 BY EXPRESS MAIL

PATENTS TRADEMARKS COPYRIGHTS (732) 634-3520

CABLE: TRADEPAT FAX: (732) 634-3511

ROBERT A GREEN

EZRA SUTTON\*

OF COUNSEL

DAVID L. DAVIS

\*WEMBER OF NJ. AND NY SARK

Assistant Commissioner for Patents Washington, D.C. 20231

File No.:

Assignee:

Dear Sir:

TOBINICK 3.0-009 (CIP) Inventor(s): Edward L. TOBINICK

None

TNFILNHIBITORS FOR THE TREATMENT OF NEUROLOGICAL,

RETINAL AND MUSCULAR DISORDERS

Enclosed herewith are the following documents in the aboveidentified application for a Letters Patent of the United States: \_\_\_Pages of Abstract W\_Verified Statement for Small Entity Status Pages of Specification Declaration, Power of Attorney & Petition \_\_Number of Claims \_\_Sheets of Drawings Two (2) return-addressed postcards (PLEASE PROVIDE FILING DATE & SERIAL NUMBER) Assignment for Recording (attached to copy of this letter)

PETITION TO MAKE SPECIAL; LIST OF PRIOR ART CITED BY APPLICANT; ARE 5 PRIOR ART PATENTS; FEE OF \$130 Check No. 3884 in the amount of \$510 (\$380 + \$130) calculated as follows: Basic Fee (\*\*Large Business \$760.00) (\*Small Business \$380.00) 380 Additional Fees: Total number of claims 99 Total number of claims in excess of 20, 79 times (\*\*\$18)(\*\$9) 711 Number of independent claims 8 Number of independent claims minus 3, 5 times (\*\*\$78)(\*\$39) 1.95 Assignment recording fee (\$40) Multiple dependent claims (\*\*\$260) (\*\$130) \$1,286 PETITION TO MAKE SPECIAL 130 TOTAL filing and assignment recording fees .416.

Respectfully submitted,

Enclosed

\_\_\_\_\_for

EZRA SÚTTON, Reg No. 25,770

Appln. No.

Will follow

ES/imt Enclosures

is claimed.

CONVENTION DATE

Priority Document:

	1	D DAVIS Esq; 78	1 1		
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Filed or I	acent no.	***************************************	. TGBINICK, M		DOCKEL NO.:
Title:	THP INH	IBITORS FOR AND MUSCULA	THE TREATMENT	OF MEUROLOG	CAL.
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	STATUS (37	CFR 1.2(f)	AND 1.27(b) -	INDEPENDENT	INVENTOR
As a below inventor as Section 41 Trademark of TREATMENT	-named inv defined i (a) and ( office with of NEUROLO	entor, I her n 37 CFR 1.9 b) of Title regard to t GICAL, RETIN	eby declare t (c) for purpo 35, Untied ( he invention of AL AND MUSCUL	hat I qualif ses of paying States Code, entitled THE AR DISORDERS	y as an independe y reduced fees und to the Patent a INBIBITORS FOR TO
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Edward	L. TOBINIC				
NAME OF IN	U16	NAME O	f inventor	name of	INVENTOR
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December 29, 1999 Date

Date

Date

10

# TNF INHIBITORS FOR THE TREATMENT OF NEUROLOGICAL, RETINAL AND MUSCULAR DISORDERS

#### RELATED APPLICATION

This is a continuation-in-part of Application Serial No. 09/256,388, filed on February 24, 1999.

#### FIELD OF THE INVENTION

The present invention relates to tumor necrosis factor (TNF) antagonists or TNF

blockers for the treatment of neurological disorders, trauma, injuries or compression; demyelinating neurological disorders, including multiple sclerosis; neurodegenerative diseases, including Alzheimer's disease; muscular disorders; and disorders of the optic nerve and retina (hereinafter "Neurologic and Related TNF Disorders"). More particularly, the TNF antagonists, TNF inhibitors or TNF blockers, are used for the treatment, prevention or amelioration of these "Neurologic and Related TNF Disorders" by modulating the action of TNF in the human body. The use of these TNF antagonists or TNF blockers results in the amelioration of these disorders and diseases and represents a novel use for this class of drugs.

#### BACKGROUND OF THE INVENTION

Neurological disorders due to demyelinating disease (e.g. multiple sclerosis), immune disease, inflammation, trauma, or compression, occur in different clinical forms depending upon the anatomic site and the cause and natural history of the physiological problem. For example, in Alzheimer's disease the brain undergoes a serious form of neurodegeneration

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Exhibit 8 Pages23-24fromIFW 09476643 077.pdf

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1490

# MANUAL OF PATENT EXAMINING PROCEDURE

REJECTION OVER A PRIOR PATENT EDWARD L. TOBINICK In re Application of: Application No. 09/476.643 December 31, 1999 Fliest THE INHIBITORS FOR THE TREATMENT OF NEUROLOGICAL Far RETINAL AND MUSCULAR DISORDERS
The owner, EDWARD L. TORINICK of QD. percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the abstutory term of any patent granted on the instant application, which would extend bayond the expiration date of the full statutory term defined in 36 U.S.C. 154 to 156 and 173, as presently shortened by any terminal disclaimer, of prior Patent No......6.,D.15.,557.... . The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns. in making the above discisimer, the owner does not discisim the terminal part of any patent gramed on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 to 156 and 173 of the prior patent, as presently shortened by any terminal disclaimer, in the event that it later: expires for failure to pay a maintanance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily discisimed in whole or terminally discisimed under 37 CFR 1.321, has all cisims cancelled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

Check either box 1 or 2 below, if appropriate.

 For submissions on behalf of an organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf of the organization.

I hereby declare that all statements made herein of my own knowledge are true and that all attainments made on information and belief are believed to be true; and further that these etatements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jacpardize the validity of the application or any patent issued thereon.

The undersigned is an attorney of record.

Signature July 20, 2000
EZRA SUTTON

Typed or printed name
Terminal disclaimer fee under 37 CFR 1.20(d) included.

\*Continuation under 37 CFR 3,73(b) is required if terminal disclaimer is signed by the assignes (owner Form PTO/SB/96 may be used for making this cartification. See MPEP § 324.

Burden Hour Statement: This form is estimated to task 0.2 hours to complete. Then will very departing upon the naseds of the individual come lay continuents on the arread of time you are required to complete this form should be sent to the Chief Information Officer, Pedest and Tradement Office, Westford, D.C. 2020.1, DO NOT SERO PEES OR COMPLETED PORGES TO THIS SECURITY, SERVICE TO: Assistance Commissioned

July 1948

1400-62

Page 8/8 ocket No. IUDINIUK 3.0-009(CIP)

. As a below named inventor, I hereby declare that:

My residence; post office address and citizenship are as stated below next to my name.

OFFICIA

3:21PM;

I belie	ve i an	the original,	first and sole inve	ntar (if only	one name is li	sted below) or	an original, fire	e and jo	int inventor	(if plurat
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(check one) & is attached hereto.

was filed on 4:
Application Serial No.
and was amended on (if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.36(a).

I hereby cláim foreign priority benefits under Title 35, United States Code, \$119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed.

#### Prior Foreign Application(s)

Priority Claimed

(Number)	(Country)	(Day/Month/Year Filed)	Yes	No
(Number)	(Country)	(Day/Month/Year Filed)	Yes	No
(Number)	(Country)	(Day/Month/Year Filed)	Yes	No

I hereby claim the benefit under Title 15, United States Code, §120 of any United States application(s) listed below and, insofar as the subject/matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 372 Code of Federal Regulations, §1.56(a) which occurred between the filling date of the prior application and the national or PCT international filling date of this application:

09/256,388	February 24. 1999	Abandoned .
(Application Serial No.) 09/275,070	(Filing Date) March 23, 1999	(Status—patented, pending, abandoned) U.S. Patent No. 6,015,557
(Application Serial No.)	(Filing Date)	(Status-patented, pending, abandoned)

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

	- 2		Ezra	Sutton,	Reg.	No.			•
							a	telephone n	o. <u>[732] 634–3520</u>
Address	all	correspon	dence to		EZRA	SUT	CON P	Α.	
							900 Rc		
	2				Wood	ride	e. New	Іетчеу	07095

I hereby déclare that all statements made herein of my own knowledge are true and that all statements made on information and belief are bilityeed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may icongraftee the validity of the apolication or any patent issued thereon.

Full name of sole or	Angeles, California Los Angeles, California Los Angeles, California	obinick, M.D.		
Inventor's signature .	x prima 1. Chis	Date J	עונ 19, 2000	
Residence LOS	Angeles, Carofornia	Cicizenship	United States o	f America
Past Office Address	100 UCLA Medical Plan	a, Suite 205		
	Los Angeles, Californ	ija 90024-6903		
	joint inventor, if any			
Second Inventor's si	gnature	Date		
Residence		Citizenship		
Part Office Address				

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Sent By: EZRA SUTTON Esq/DAVID DAVIS Esq; 732 634 3511; Jul-21-00 3:20PM; Page 1 Exhibit 9 Pages18-18fromIFW 09476643 077.pdf LAW OFFICES EZRA SUTTON, P. A. FAX RECEIVED A PROFESSIONAL CORPORATION JUL 2 4 2000 PLAZA 9 900 ROUTE 9 GROUP 1600 PATENTS POODBRIDGE NEW JERSEY 07095 EZRA SUTTON" TRADEMARKS HOTTUE HEBLOL COPYRIGHTS OF COUNSEL ROBERT A. CREEN (732) 634-3520 DAVID L. DAVIS FAX: (732) 634-3511 FROM: FAX NO. 1-732-634-3520 PHONE: TOTAL NUMBER OF PAGES:

Jul-21-20 3:20PM;

Group Art Unit 1614

July 20, 2000

Examiner William R. A. Jarvis

**HFFIC!** 

TOBINICK 3.0-009 (CIP)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BY FAX AND MAIL

In re patent application of: EDWARD L. TOBINICK

Scrial No.: 09/476,643

Filed: December 31, 1999

For: TNF INHIBITORS FOR THE TREATMENT OF NEUROLOGICAL , :

RETINAL AND MUSCULAR DISORDERS

Assistant Commissioner for Patents Washington, D.C. 20231

AMENDMENT

Sir:

This is in response to the first Office Action.

IN THE SPECIFICATION:

Please amend the first sentence of the specification as follows:

09/275.070

- This is a continuation-in-part of Application Serial No. 09/256,388, filed on U.S. Patent 6,015,55%, which is a continuation-in-part of March 23, 1999

February 24, 1999, now abandoned, and Application Scrial No. 09/275,070, now U.S. Patent 09/256,388, filed February 24, 1999, now abandoned No. 6.015:557.

FRI 15:19 [TX/RX NO 6334] @002

#### THE INHIBITORS FOR THE TREATMENT OF NEUROLOGICAL DISORDERS

#### RELATED APPLICATION

This application is a continuation-in-part of application Ser. No. 09/275,070, filed on Mar. 23, 1999, now U.S. Pat No. 6,015,557, which is a continuation-in-part of application Ser. No. 09/256,388, filed Feb. 24, 1999 new abandoned.

#### FIELD OF THE INVENTION

The present invention relates to tumor necrosis factor (TNF) antagonists or TNF blockers for the treatment of neurological disorders, trauma, injuries or compression; demyelinating neurological disorders, including multiple 15 sclerosis, neurodegenerative diseases, including Alzheimer's disease; muscular disorders; and disorders of the optic nerve and retina (hereinafter "Nenrologic and Related TNF Disorders"). More particularly, the TNF antagonists, TNF inhibitors or TNF blockers, are used for the treatment, 20 prevention or amelioration of these "Neurologic and Related TNF Disorders" by modulating the action of TNF in the human body. The use of these TNF antagonists or TNF blockers results in the amelioration of these disorders and diseases and represents a novel use for this class of drugs. 25

#### BACKGROUND OF THE INVENTION

Neurological disorders due to demvelinating disease (e.g. multiple sclerosis), immune disease, inflammation, trauma, or compression, occur in different clinical forms depending upon the anatomic site and the cause and natural history of the physiological problem. For example, in Alzheimer's disease the brain undergoes a serious form of neurodegencration of unknown ctiology. Common to all of these disorders is the fact that they can cause permanent neurological damage, that damage can occur rapidty and be irreversible, and that current treatment of these conditions is unsatisfactory, often requiring surgery and/or the use of pharmacologic agents, which are often not completely successful

These nemological conditions include acute spinal cond trauma, spinal cord compression, spinal cord hematoma, cord contusion (these cases are usually traumatic, such as motorcycle accidents or sports injuries); nerve compression, 45 to this task because they have been demonstrated to drathe most common condition being a herniated disc causing sciatic nerve compression, neuropathy, and pain; but also including cervical disc herniation, causing nerve compression in the neek; acute or chronic spinal cord compression from cancer (this is usually that to metastases to the spine, 50 your system associated with autoimmune disease, demyelisuch as from prostate, breast or lune cancer); autoimmune disease of the pervous system; and degreelinating diseases, the most common condition being multiple sclerosis.

Steroid drugs such as cortisone that are used to treat many of the aforementioned neurological problems and conditions are particularly hazardous because they are used either at high dosage, with a corresponding increasing risk of side effects, or because they are used chronicalty, also increasing their adverse effects. Lastly, steroids are only partially effective or completely ineffective.

Tumor necrosis factor (TNF), a naturally occurring cytokine, plays a central role in the inflammatory response and in immune injury. TNF is formed by the cleavage of a precursor transmembrane protein, forming soluble molecules which aggregate to form trimolecular complexes. 65 These complexes then hand to recentors found on a variety of cells. Binding produces an array of pro-inflammatory

effects, including release of other pro-inflammatory cytokines, including interlenkin (II)-6, II-8, and II-1; release of matrix metalloproteinases; and up regulation of the expression of endothelial adhesion molecules, further amplifying the inflammatory and immune cascade by attracting lenkocytes into extravascular tissues. TNF is now

well established as key in the pathogenesis of theumatoid

arthritis (RA) and Crohn's Disease.

Specific inhibitors of TNF, only recently commercially 10 available, now provide the possibility of therapeutic intervention in TNF mediated diseases. Dramatic therapeutic success has already been demonstrated with infliximab, a changeric anti-TNF monoclonal antibody (mAb), in treating Crohn's Disease and RA; and with ctanercept, a recombinam fusion protein consisting of two soluble TNF receptors joined by the Fe fragment of a human IgG1 molecule, in treating RA and Psoriatic Arthritis. Other specific anti-TNF agents are under development, including D2E7 (a human anti-TNF mAb), CDP 571 (a chimeric, but 95% humanized, anti-TNF mAb), and a pegylated soluble TNF type 1 receptor. Additionally, thatidomide has been demonstrated to be a potent anti-TNF agent. Further, anti-TNF therapies may include gene therapy and the development of selective inhibitors of the TNF-alpha converting enzyme.

As with other organ systems, TNF has been shown to have a key role in the central nervons system. There is a need for TNF inhibitors that will open a new realm of therapentic possibilities for a wide variety of neurological and related disorders. These disorders are diverse and include inflamin matory and autoimmune disorders of the nervous system, including multiple sclerosis, Guillain Barre syndrome, and myasthenia gravis; degenerative disorders of the nervous system, including Alzheimer's disease, Parkinson's disease and Huntington's disease; disorders of related systems of the 35 retins and of muscle, including optic neuritis, macular degeneration, diabetic retinopathy, dermatomyositis, amyotrophic lateral selerosis, and muscular dystrophy; and ininries to the nervous system, including transnatic brain injury, acute spinal cord injury, and stroke

The limited ability of the body to effect repair after injury to the nervous system, the devastating nature of these diseases and the lack of effective therapy all highlight the importance of early therapy aimed at preventing or limiting neuronal destruction. Anti-TNF therapies are ideally suited matically limit inflammation by interrupting the inflammatory cascade at a fundamental level

There remains a need for a new pharmacologic treatment of these aforementioned physiological problems of the nernating diseases, neurodegenerative diseases, trauma, injuries and compression with the pharmacological use of TNF antagonists or TNF blockers, which are greatly beneficial for the large number of patients whom these conditions affect. 55 Drugs which are powerful TNI blockers are stanercept, infliximat, pegylated soluble TNF Receptor Type I (PEGs TNF-R1), other agents containing soluble TNF receptors, CDP571 (a humanized monoclonal anti-TNF-alpha autibodies), thalidomide, phosphodiesterase 4 (IV) inhibitor 60 thalidomide analogues and other phosphodiesterase IV intribitors. Etanercept or infliximab may be used for the immediate, short term and long term (acute and chronic) blockade of TNF in order to minimize neurological damage mediated by TNF dependent processes occurring in the aforementioned neurological disorders. The use of these TNF antagonists or TNF blockers would result in the amelioration of these physiological neurological problems.





## EZRA SUTTON, P. A.

A PROFESSIONAL CORPORATION PLAZA 9

DAG POUTE O

FZRA SUTTON\* OF COUNSEL ROBERT A GREEN DAVID L DAVIS

\*MEMBER OF NU AND NY BARS

WOODBRIDGE, NEW JERSEY 07095

March 23, 1999

BY EXPRESS MAIL

DATEMPS TRADEMARKS COPYRIGHTS

(732) 634-3520 CABLE: TRADEPAT FAX: (732) 634-35H

Assistant Commissioner for Patents Washington, D.C. 20231

> File No. : Inventor(s): Title:

TOBINICK 3.0-007 (CIP) Dr. Edward L. Tobinick

TUMOR NECROSIS FACTOR ANTAGONISTS FOR THE TREATMENT OF NEUROLOGICAL DISORDERS

Assignee: None

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12 Pages of Specification 
14 Pumber of Claims 
15 Pages or Abstract X\_Verified Statement for Small Entity State 
16 Declaration, Power of Attorney & Petition 
17 Two (2) return-addressed obstracts X Verified Statement for Small Entity Status Conone Sheets of Drawings (PLEASE PROVIDE FILING DATE & SERIAL NUMBER) Whome Assignment for Recording (attached to copy of this letter)

X PETITION TO MAKE SPECIAL; LIST OF PRIOR ART CITED BY APPLICANT; 3 PRIOR ART

PATENTS; FEE (\$130 Check No. 300 lin the amount of \$753.00 , calculated as follows:

Basic Fee (\*\*Large Business \$760.00) (\*Small Business \$380.00) Additional Fees: Total number of claims

\$380.00

Total number of claims in excess of 20, 27 times (\*\*\$18)(\*\$9) 243.00 Number of independent claims 2 Number of independent claims minus 3, --times (\*\*\$78)(\*\$39) Assignment recording fee (\$40)

\$753.00

TOTAL filing and assignment recording fees

Multiple dependent claims (\*\*\$260) (\*\$130)

\$623.00 PETITION TO MAKE SPECIAL FEE 130.00

CONVENTION DATE \_\_\_\_ for Appln. No. is claimed. Priority Document:

Enclosed Will follow

EZRA SUTTON, Reg No. 25,770

Respectfully submitted,

ES/jmt Enclosures 10

5

# TUMOR NECROSIS FACTOR ANTAGONISTS FOR THE TREATMENT OF NEUROLOGICAL DISORDERS

#### RELATED APPLICATION

This is a continuation-in-part of Application Serial No. 09/956,388, filed on February 24, 1999.

#### FIELD OF THE INVENTION

The present invention relates to tumor necrosis factor (TNF) antagonists or TNF blockers for the treatment of neurological disorders, trauma, injuries or compression; or demyelinating neurological disorders, including multiple sclerosis. More particularly, the TNF antagonists or TNF blockers, with or without the concurrent administration of methotrexate or Leflunomide, are used in a new treatment of these disorders by inhibiting the action of TNF in the cells of the human body. The use of these TNF antagonists or TNF blockers with methotrexate or Leflunomide results in the amelioration of these neurological conditions.

#### BACKGROUND OF THE INVENTION

Neurological disorders due to demyelinating disease (e.g. multiple sclerosis), immune disease, inflammation, trauma, or compression, occur in different clinical forms depending upon the anatomic site and the cause and natural history of the physiological problem. Common to all of these disorders is the fact that they can cause permanent neurological damage, that damage can occur rapidly and be irreversible, and that current treatment of these conditions is unsatisfactory, often requiring surgery

20

25

As a below named inventor, I hereby in that;

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural
names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled TUMOR NECROSIS FACTOR ANTACONISTS FOR THE TREATMENT , the specification of which
TUMOR NECROSIS FACTOR ANTACONISTS FOR THE TREATMENT the specification of which
OF NEUROLOGICAL DISORDERS

(check one)xix is attached hereto.

U	was filed on	a
	Application Serial No.	
	and was amended on (if applicable	le)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)			Priority	Claimed
(Number)	(Country)	(Day/Month/Year Filed)	Yes	No
(Number)	(Country)	(Day/Month/Year Filed)	Yes	No
(Number)	(Country)	(Day/Month/Year Filed)	Yes	No

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Itile 35, United States Code, §1212, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filling date of the prior application and the national or PCT international filing date of this application:

09/256,388	. 24 February 1999	pending
(Application Serial No.)	(Fliing Date)	(Status=patented, pending, abandoned)
(Application Serial No.)	(Filing Date)	(Status-patented, pending, abandoned)

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like to made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may leopardize the validity of the application or any patent issued thereon.

such willful false statements may jeopardize the validity of the application of any patent issued thereon.	
Full name of sole or first inventor / Dr. Edward L. TOBINICK	
Inventor's signature X Date 3-20-79	
Inventor's signature X 20 Date 3-20-79 Residence Los Angolos, California 90024-69 Cheenship United States o	f America
Post Office Address 100 UCLA Medical Plaza, Suite 205	
Los Angeles, California 90024-6903	
Full name of second joint inventor, if any Arthur Jerome TOBINICK	
Residence Los Angeles, Calibornia 90024 69 Chizenship United States o	
Residence Los Angeles, California 90024-69 Chizenship United States o	f America
Post Office Address 100 UCLA Medical Plaza, Suite 205	
Los Angeles, California 90024-6903	

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	Ŋχ	Edward	L.	TOBINICK

Arthur J.

Attorney's TOBINICK Docket No.: 3.0.007 (618)

Filed or Issued: TUMOR NECROSIS FACTOR ANTAGONISTS FOR Title: TREATMENT OF NEUROLOGICAL DISORDERS

Applicant or Patentee:

Serial or Patent No .: \_

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 CFR 1.2(f) AND 1.27(b) - INDEPENDENT INVENTOR

As a below-named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, to the Fatent and

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I have not assigned, granted, conveyed, or licensed and am under no obligation, under contract or law to assign, grant, convey, or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern, or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

X }	no	such	person,	conc	era,	or	organiza	ation	
- 1	pe	rsons.	concer	ns, o	ror	gan:	izations	listed	below*

Separate verified statements are required from each named person, \*NOTE: concern, or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

ADDRESS								
[ ] INDIVIDUAL	[ ]	SMALL	BUSINESS	CONCERN	1	1	NONPROFIT	ORGANIZATION
FULL NAME								
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I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Dr. Edward L. TOBINICK NAME OF INVENTOR	NAME OF INVENTOR	NAME OF INVENTOR
X Dunch fort	x Cottnut Box	ul
Signature of Inventor	Signature of Inventor	Signature of Inventor
3-20-99	3-20-99	
Date	Date	Date

TOBINICK 3.0-007 (CIP)

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:
DR. EDWARD L. TOBINICK, et al

Serial No.

Filed:

FOR: TUMOR NECROSIS FACTOR ANTAGONISTS FOR THE TREATMENT OF NEUROLOGICAL DISORDERS

Group Art Unit

Examiner

March 23, 1999



Assistant Commissioner for Patents Washington, D.C 20231

## PETITION TO MAKE SPECIAL (MPEP Section 708.02)

Sir:

Applicant hereby files this Petition to make special this application for purposes of examination and payment of the issue fee, on the grounds of a pre-examination search. Applicant also submits the petition fee.

The application presents claims directed to a single invention. In case the Examiner believes that there is more than one invention, applicant hereby elects without traverse Claims 27 to 47.

## SEARCH AREAS

A pre-examination seasces was made of the records of the U.S.

Patent Office by applicants attorney, Ezra Sutton. The field of search included Class 424, Subclasses 85.1, 133.1, 134.1, 143.1,

04/01/1999 PALLEN 03 FC:122 144.1, 145.1, and 158.1; Class 435, Subclasses 69.1, 69.7, 172.3, and 240.27; and Class 530, Subclasses 350, 351, 387.1, 387.3, 388.2, 388.23, 388.4, 866, and 868. Also, a computer search was performed using the terms TNF and tumor necrosis factor.

#### INVENTION SEARCHED

A method for inhibiting the action of TNF for treating neurological conditions in a human by administering a TNF antagonist for reducing damage to neuronal tissue or for modulating the immune response affecting neuronal tissue of the human. The TNF antagonist administered is selected from the group consisting of etanercept and infliximab. The TNF antagonist is administered subcutaneously, intravenously, intrathecally, or intramuscularly.

Methotrexate or Leflunomide may be administered concurrently with the TNF antagonist for demyelinating diseases and certain other neurological disorders.

#### PATENTS SELECTED IN SEARCH

U.S. Patent Nos.: 5,605,690

5,656,272

5,795,967

A copy of each patent is enclosed.

#### DISCUSSION OF PATENTS

U.S. Patent No. 5,605,690 discloses using TNF antagonists to suppress TNF-dependent inflammatory diseases, such as arthritis. However, this reference does not disclose treating the specific neurological disorders claimed in the present application.

U.S. Patent No. 5,656,272 discloses using TNF antagonists to treat Crohn's disease. However, this reference does not disclose treating the specific neurological disorders claimed in the present application.

U.S. Patent No. 5,795,967 discloses using TNF antagonists to treat certain autoimmune diseases, such as arthritis, systemic lupus, and Crohn's disease. However, this reference does not disclose treating the specific neurological disorders claimed in the present application.

#### CONCLUSION

None of the prior art patents disclose or teach the specific subject matter recited in independent Claims 1 or 27, or render them obvious. Accordingly, this Petition should be granted.

Respectfully submitted,

EZRA SUTTON, P.A.

EZRA SUTTON Reg. No. 25.770

Plaza 9, 900 Route 9 Woodbridge, New Jersey 07095 (732) 634-3520

ES/jmt

Enclosures

## rnmea 01/05/2000

SERIAL NUMBER	FILING DATE CLASS	5	GROUP ART UNIT	ATTORN	EY DOCKET NO						
09/275,070	03/23/1999	424	1614	тов	INICK-3.0						
	APPLICANY EDWARD L TOBINICK, LOS ANGELES, CALIFORNIA; ARTHUR JEROME TOBINICK, LOS ANGELES, CALIFORNIA.										
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#### TUMOR NECROSIS FACTOR ANTAGONISTS FOR THE TREATMENT OF NEUROLOGICAL DISORDERS

#### RELATED APPLICATION

This is a continuation-in-part of application Ser. No. 09/256.388, filed on Feb. 24, 1999, now abandoned.

#### FIELD OF THE INVENTION

The present invention relates to tuttor necrosis factor (TNF) antagons or TNF blockers for the treatment of neurological disorders, trauma, injuries or compression; or demyeliarities neurological disorders, including multiple sclerosis. More particularly, the TNF antagonists or TNE 18 blockers, with or without the concernment administration of methoticizate or Leiburomide, are used in a new traumout of these disorders by inhibiting the action of TNF in the cells of the human body. The use of these TNF amagonists or TNF blockers with methoticizate or Leiburomide resolts in the 26 anniforation of these neurological conditions.

#### BACKGROUND OF THE INVENTION

Neumbagical disorders due to demyelinating disease (e.g. untiliple selections), immune disease, inflammatint, trauma, a for compression, occur in different clinical forms depending upon the anatomic site und the causes and natural history of the physiological problem. Common to all of these disorders is the fact that they can cause permanent neurological damage, that damage can soccur tapidly and be invertible, and that current treatment of these endolfions is and that current treatment of these endolfions is plantaneologic agents, which are other ton compiletely energy excessful.

These neurological conditions include acute spinal cord insuma, spinal curd compression, spinal cord hematoma, spinal curd compression, spinal cord hematoma, curd combission flowes cases are usually Insumatic, such as motoreyde accidents or sports injuries), nerve compression, the most examine or outline being a fertirated disc causing an sciatis nerve compression, neuropathy, and pain, but also including cervical disc hemation, causing nerve compression in the neck; carpat tunnel syndrome (geon-RA), neute or fortherie spinal cord compression from cancer (this is usually due to mensuasses to the spine, such as form prostate, breast or ling cancery, aunitemate discase of the nervous system; and demyelinating discases; the mass comman condition besite multible sclerosis.

Steroid drugs such as cortisone that are used to treat the afternmentioned neutrological problems and conditions are 90 particularly hazardous because they are used either at high doesage, with a corresponding increasing risk of sake effects or hexause they are used chumically, also increasing their adverse effects. Lastly, secretisk are only partially effective or completely inclined inc.

Their remains a need for a new pharmacologic treatment of these affectionationed physiological modeluses of the networks of these affectionationed physiological modeluses of the networks system associated with autoimment disease, demyelismating diseases, transma, injuries and compression with the pharmacological use of TNF sutagonish or TNF blockers, we which are greatly beneficial for the lange number of patients which in these conditions affect. Two new drugs which are powerful TNF blockers are extensivery and utilizational bitanic except or infliximab may be used for the numediate, short seem and long term (acue and chronic) blockade of TNF in 68 o'dor to maintaix, neurologic damage mediated by TNF deeptled to processes occurring in the aforementment neuron and manufactured or the process of the proces

rological disorders. The use of these TNF antagonists or TNF blackers would result in the amelioration of these physiological neurological problems. Concurrent administration of methonessate or Lethonemide with either cameracept or infliximals as the preferrent treatment for demyelimang diseases and certain other neurological disorders.

#### DESCRIPTION OF THE PRIOR ART

Pharmacologic chemical substances, compounds and agents which are used for the treatment of penrological disorders, trauma, injuries and compression having various organic structures and metabolic functions have been disclosed in the prior art. For example, U.S. Pat. Nos. 5,756,482. and 5,574,022 to ROBERTS et al disclose methods of attenuating physical damage to the nervous system and to the spinal cord after injury using steroid hormones or steroid precursors such as pregnenoloue, and pregnenoloue sulfate in conjunction with a non-steroidal anti-inflammatory substance such as indomethacin. These prior art patents do not teach the use of a TNF antagonist or TNF blocker for the suppression and inhibition of the action of TNF in the human body to treat neurological disease, traums, injury or compression, or autoimmune neurologic disease as in the present invention.

U.S. Pat. No. 5,005,000 to JACOHS discloses: a method for treating TNI-dependent inflammatory discess such as arbirits by administering a TNE autogonist, such as soluble tuman TNE (a sequence of animo sciels), to a lumina. This prior air patent does not teach the use of a TNP antagonist or TNP theeker for the suppression and inhibition of the action of TNP in the human body to treat neurological disease, trauma, finary or compression, or demyelimating neurologic disease, rusuma, finary or compression, or demyelimating neurologic disease, as in the present invention.

U.S. Pat. No. 5.056,272 to LE et al discloses methods of retaing TNF-aipha-mediated Crohn's disease using chimeric anti-TNF antibodies. This prior art patient does not teach the use of a TNF antagonist or TNF blocker for the suppression and inhibition of the actino d TNF in the human body to treat neurological traums, injury or compression, or antionimume neurological traums, and the present invention.

U.S. Pat. No. 5.650,306 discloses a method of treating mittiple sclerosis (MS) by blocking and inhibiting the action of TNF in a patient. This prior art patient does not teach the use of the TNF antagonist as in the present invention.

None of the prior art patents disclose or teach the use of the INF attaggments or INF blocker of the present meetition with the concurrent administration of methoricizate or Inchunentide for suppression and inhibition of the action of TNF in a timma to treat neurological disease, tumum, nijery or compression, or demyelinating neurologic disease, in which the INF antagonist gives the patient a better opportunity to heal, slows disease, progression, prevents neurological damage, or otherwise improves the patier's health.

Accordingly, it is an object of the present invention to sprovide a TNA antagonis, with or without the concurrent idministration of methoricyate or Leftmonitel, for a new plantacologic treatment of neurological disorders, trainus, injuries and compression affecting the nervous system of the human backy, or demyeliaring pentrologic dissease, such that or the second period of the period of the pentrological disease, when that or the second pentrological disease, when the or the period pentrological disease, when the feet the second pentrological disease, when the result in the american pentrological disease.

Another object of the present invention is to provide a TNF antagement, with or without the concurrent administration of methoristic of Leibnenide, for providing suppression and inhibition of the sesion of TNF in a human to trest neurological might, channe or comprossion, or demyelinaing neurologic disease.

## DE RATION FOR PATENT APPLICATION

Docket No. TOBINICK

As a below named inventor, I hereby declare that

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled TUMOR NECROSIS FACTOR ANTAGONISTS FOR THE TREATMENT \_\_\_\_\_, the specification of which OF NEUROLOGICAL DISORDERS (check one) 🔯 is attached hereto. was filed on Application Serial No. and was amended on (if applicable). I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above. I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, \$1,56(a). I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed: Prior Foreign Application(s) Priority Claimed (Country) (Day/Month/Year Filed) No (Number) (Country) (Day/Month/Year Filed) No (Number) No (Number) (Country) (Day/Month/Year Filed) Yes Ö Thereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner promided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application: (Application Serial No.) (Filing Date) (Status-patented, pending, abandoned) (Application Serial No.) (Filing Date) (Status-patented, pending, abandoned) Thereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Frademark Office connected therewith: Ezra Sutton, Reg. No. 25,770 Address all telephone calls to at telephone no. Address all correspondence to EZRA SUTTON, P.A. Plaza 9, 900 Route 9

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Woodbridge, New Jersey 07095

Full name of sole or first inventor Inventor's signature . Date ... Angeles, California 90024-6 49tZenship Los United States of America 100 UCLA Medical Plaza, Suite 205 Post Office Address Los Angeles, California 90024-6903 ARTHUR JEROME TEBINCK Full name of second joint inventor, if any .... Second Inventor's signature Cotton Come top Dale February 21, 1999 Residence LOS ANCELES, CALIAMIA 90024-6903 Citizenship USA Post Office Address 100 UCLA MEDICAL PLAZA, SUTTE 205 LOS ALGUES, CALIGRAMA 90024-6903

Applicant or Patentee: Dr. Edward L. TOBINICK AATRAC J. Testalica Attorney's Serial or Patent No.:
Filed or Issued: TOBINICK 3.0-0
Title:TUMOR_NECROSIS_FACTOR_ANTAGONISTS_FOR_THE
TREATMENT OF NEUROLOGICAL DISORDERS VERIFIED SYMMETHY (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 CFR 1.2(f) AND 1.27(b) ~ INDEPENDENT INVENTOR
As a below-named inventor, I hereby declare that I qualify as an independen inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees unde Section 41(a) and (b) of fitle 35, Untied States Code, to the Patent an Trademark office with regard to the invention entitled TUNOR MECROSIS FACTOR NATHORNISTS FOR THE TREATMENT OF MEUROLOGICAL DISORDERS
described in:  [X] the specification filed herewith  [] Application Serial No, filed  [] Patent No, issued
I have not assigned, granted, conveyed, or licensed and am under no obligation under contract or law to assign, grant, convey, or license, any rights in th inpention to any person who could not be classified as an independent invento under 37 CFR 1.9(c) if that person had made the invention, or to any concer which would not qualify as a small business concern under 37 CFR 1.9(d) or no other contraction under 37 CFR 1.9(e).
కోవch person, concern, or organization to which I have assigned, granted conveyed, or licensed or am under an obligation under contract or law to assign grant, convey, or license any rights in the invention is listed below:
[X] no such person, concern, or organization [] [] persons, concerns, or organizations listed below*
*NOTE: Separate verified statements are required from each named person concern, or organization having rights to the invention averrinto their status as small entities. (37 CFR 1.27)
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[] INDIVIDUAL [] SMALL BUSINESS CONCERN [] NONPROFIT ORGANIZATION I acknowledge the duty to file, in this application or patent, notification or any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate (.37 CFR 1.28(b))
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful fals statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.
Dr. Edward L. TOBINICK AFTUR JERONE TOBINICK
NAME OF INVENTOR NAME OF INVENTOR

Feb 21,1999 Date Signature of Inventor

Date

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#### DECLARATION FOR PATENT APPLICATION

Docket No. TOBINICK 3.0-007

As a below named inventor, I hereby declare that:

Inventor's signature

X &L

My residence, post office address and citizenship are as stated below next to my name. I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled TUMOR NECROSIS FACTOR ANTAGONISTS FOR THE TREATMENT , the specification of which OF NEUROLOGICAL DISORDERS (check one) & is attached hereto. was filed on Application Serial No. and was amended on (if applicable). I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above. I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, \$1.56(a). I hereby claim foreign priority benefits under Title 35, United States Code, \$119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed: Prior Foreign Application(s) Priority Claimed (Number) (Country) (Day/Month/Year Filed) Yes No No (Number) (Country) (Day/Month/Year Filed) (Day/Month/Year Filed) No (Number) (Country) Lhereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner proadded by the first paragraph of Title 35, United States Code, \$112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national of PCT international filing date of this application: (Application Serial No.) (Filing Date) (Status-patented, pending, abandoned) (Status-patented, pending, abandoned) (Application Serial No.) (Filing Date) I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patem and Frademark Office connected therewith: Ezra Sutton, Reg. No. 25.770 at telephone no. \_ Address all telephone calls to Address all correspondence to EZRA SUTTON, P.A. Plaza 9, 900 Route 9 Woodbridge, New Jersey 07095 I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon. Full name of sole or first inventor

Residence Los Angeles. California 90024-69913enship United States of America 100 UCLA Medical Plaza, Suite 205 Los Angeles, California 90024-6903 ARTHUR JERGYE TUSINICK Full name of second joint inventors if any ... Date February 21, 1999 Second Inventor's signature College Second Inventor's signature Residence 105 ANGLES, CALIFORNA 90024-6903 Citizenship USA Post Office Address 100 UCLA MEXCE PLAZA, SUITE 205 LOS ANGUES, CALIFORNIA 90034-6903

FEBRUARY 21, 1999

LAW OFFICES

#### EZRA SUTTON, P. A. A PROFESSIONAL CORPORATION

PLAZA 9 900 ROUTE 9

WOODBRIDGE, NEW JERSEY 07095

February 24, 1999

BY EXPRESS MATI.



PATENTS TRADEMARKS COPYRIGHTS

(732) 634-3520 CABLE: TRADEPAT FAX: (732) 634-3511

\*MEMBER OF N.J. AND N.Y. BARS Assistant Commissioner for Patents Washington, D.C. 20231 TOBINICK 3.0-007 File No.: Dr. Edward L. Tobinick Inventor(s): TUMOR NECROSIS FACTORS ANTAGONISTS FOR Title: THE TREATMENT OF NEUROLOGICAL DISORDERS 3.3 None Assignee: ŒDear Sir: Enclosed herewith are the following documents in the above-Midentified application for a Letters Patent of the United States: 1\_Pages of Abstract \_x\_Verified Statement for Small Entity Status Pages of Abstract x verified Statement 101 Small 2010.

Replacement 101 Small 2010. 24 Number of Claims
Two (2) return-addressed postcards
PT Sheets of Drawings (PLEASE PROVIDE FILING DATE & SER (PLEASE PROVIDE FILING DATE & SERIAL NUMBER) Assignment for Recording (attached to copy of this letter) Check No. in the amount of \$416.00 , calculated as follows: Basic Fee (\*\*Large Business \$760.00) (\*Small Business \$380.00) \$380..00 Additional Fees: Total number of claims 24 Total number of claims in excess of 20, 4 times (\*\*\$18)(\*\$9) 36.00 Number of independent claims \_\_1\_ Number of independent claims minus 3, \_- times (\*\*\$78)(\*\$39) Assignment recording fee (\$40) Multiple dependent claims (\*\*\$260) (\*\$130) \$416.00 TOTAL filing and assignment recording fees CONVENTION DATE \_\_\_\_\_\_ for \_\_\_\_\_Appln. No.\_\_\_\_\_ is claimed.

ES/imt Enclosures

AA SUTTON\*

OF COUNSEL IF

BERT A. GREEN DVID L. DAVIS

EZRA SUTTON, Reg No. 25,770

tespectfully submitted,

Priority Document: \_\_\_\_Enclosed \_\_\_Will follow

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#### TUMOR NECROSIS FACTOR ANTAGONISTS FOR THE TREATMENT OF NEUROLOGICAL DISORDERS

#### FIELD OF THE INVENTION

The present invention relates to tumor necrosis factor (TNF) antagonists or TNF blockers for the treatment of neurological disorders, trauma, injuries or compression: or autoimmune neurological disorders. More particularly, the TNF antagonists or TNF blockers are used in a new treatment of these disorders by inhibiting the action of TNF in the cells of the human body. The use of these TNF antagonists or TNF blockers results in the amelioration of these neurological conditions.

#### BACKGROUND OF THE INVENTION

Neurological disorders due to demyelinating disease, immune disease, inflammation, trauma, or compression, occur in different clinical forms depending upon the anatomic site and the cause and natural history of the physiological problem. Common to all of these disorders is the fact that they can cause permanent neurological damage, that damage can occur rapidly and irreversible, and that current treatment of these conditions is unsatisfactory, often requiring surgery and/or the use pharmacologic agents, which are often not completely successful.

These neurological conditions include acute spinal cord trauma, spinal cord compression, spinal cord hematoma, cord contusion (these cases are usually traumatic, such as motorcycle accidents or sports injuries); nerve compression, the most common condition being a herniated disc causing sciatic nerve compression,

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Exhibit 15\_Pages18-20fromFileRistory\_09-266388.pdf



# UNITED STATE DEPARTMENT OF COMMERCE Patent and Tracemark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/256,	388 02/2	1799 TOBINICK	E 3.0-007

EZRA SUTTON HM12/0927 EXAMINER

EZRA SUTTON JARVIS, W
PLAZA 9 ROUTE 9
WOODBRIDGE NJ 07095 ARTUNIT PAPER NUMBER

ART UNIT PAPER NUMBER
1614

DATE MAILED:

09/27/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Notice of Abandonment

Application No. 09/256,388

Appli

Examiner William R. A. Jarvis Tobinick

Group Art Unit 1614



		polication is abandoned in view of:
		plicant's failure to timely file a proper response to the Office letter mailed on
		A response (with a Certificate of Mailing or Transmission of) was received on, which is after the expiration of the period for response (including a total extension of time of, which expired on
		A proposed response was received on, but it does not constitute a proper response to the final rejection.
		(A proper response to a final rejection consists only of: a timely filed amendment which places the application in condition for allowance; a Notice of Appeal; or the filing of a continuing application under 37 CFR 1.62 (FWC)).
		No response has been received.
O		plicant's failure to timely pay the required issue fee within the statutory period of three months from the mailing date the Notice of Allowance.
		The issue fee (with a Certificate of Mailing or Transmission of) was received on
	$\Box$	The submitted issue fee of \$ is insufficient. The issue fee required by 37 CFR 1.18 is \$
		The issue fee has not been received.
		the state of the s
LJ		plicant's failure to timely file new formal drawings as required in the Notice of Allowability.
		Proposed new formal drawings (with a Certificate of Mailing or Transmission of) were received on
		The proposed new formal drawings filed are not acceptable.
		No proposed new formal drawings have been received.
	th	e express abandonment under 37 CFR 1.62(g) in favor of the FWC application filed on
X		e letter of express abandonment which is signed by the attorney or agent of record, the assignee of the entire erest, or all of the applicants.
	th:	e letter of express abandonment which is signed by an attorney or agent (acting in a representative capacity under / CFR 1.34(a)) upon the filing of a continuing application.
	th fo	e decision by the Board of Patent Appeals and Interferences rendered on and because the period r seeking court review of the decision has expired and there are no allowed claims.
	th	e reason(s) below:
		Dilliam Jami
		WILLIAM R A JARVIS

#### MANUAL OF PATENT EXAMINING PROCEDURE

agreeing to the change of inventorship in the patent; such statement must comply with the remirements of 37 CFR 3.73(b); and (4) the fee set forth in 37 CFR 1.20(b). This petition lacks item(s) 171

1481.03

Supervisory Patent Examiner. Art Unit 191.

Technology Center [10]

## 1111 Examiner Note:

- 1. If each of the four specified items has been submitted but one or more is insufficient, the petition should be denied. See paragraph 10.17. However, if the above noted deficiency can be cured by the submission of a renewed petition, a dismissal would be appropriate.
- If the petition includes a request for suspension of the rules (37 CFR 1.183) of one or more provisions of 37 CFR 1.324 that are required by the statute (35 U.S.C. 256), form paragraph 10.18 should follow this form paragraph.
- 3. In bracket 7, pluralize as necessary and insert the item numben's) which are missing.
- 4 In bracket 11, insert correspondence address of record. This form paragraph is printed with the USPTO letterhead.

§ 10.17 Petition Under 37 CFR 1.324, Denied

In re Patent No. 111 Issue Date: [2]

DECISION DENYING PETITION

37 CFR 1.324 Appl No : [3] Filed: [4]

For. [5]

This is a decision on the petition filed [6] to correct inventorship under 37 CFR 1.324.

The petition is denied

Supervisory Patent Examiner.

Art Unit 191.

Technology Center [10]

10.14 or 10.20, rather than being denied.

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#### Examiner Note:

- 1. In bracket 7, a full explanation of the deficiency must be provided.
- 2. If the petition lacks one or more of the required parts set forth in 37 CFR 1324, it should be dismissed using form paragraph
- In bracket 11, insert correspondence address of record.
- 4. This form paragraph is printed with the USPTO letterhead.
- \$ 10.18 Waiver of Requirements of 37 CFR 1.324 Under 37 CFR 1.183, Dismissed

Suspension of the rules under 37 CFR 1.183 may be granted for any requirement of the regulations which is not a requirement of the statutes. In this instance, 35 U.S.C. 256 requires [1]. Accordingly, the petition under 37 CFR 1.183 is dismissed as

#### Examiner Notes

- 1. This form paragraph should follow form paragraph 10.16 whenever the petition requests waiver of one or more of the provisions of 37 CFR 1 324 that are also requirements of 35 U.S.C. 256
- 2. If the petition requests waiver of requirements of 37 CFR 1.324 that are not specific requirements of the statute (i.e., the fee or the oath or declaration by all inventors), the application must be forwarded to a petitions attorney in the Office of the Deputy Commissioner for Patent Exammation Policy for decision.

## 1481.03 Correction of 35 U.S.C. 119 and 35 U.S.C. 120 Benefits IR-71

CORRECTION TO PERFECT CLAIM FOR 35 U.S.C. 119 (a)-(d) AND (f) BENE-FITS

See MPEP § 201.16 for a discussion of when 35 U.S.C. 119 (a)-(d) and (f) benefits can be perfected by certificate of correction.

- CORRECTION AS TO 35 U.S.C. 120 AND 35 U.S.C. 119(e) RENEFITS
- For Applications Filed \*\*>Before< November 29, 2000

For applications filed \*\*>before< November 29, 2000, it is the version of 37 CFR 1.78, which was in effect as of November 29, 2000, that applies. The pre-November 29, 2000 version reads as follows:

37 CFR 1.78. Claiming benefit of varler filing date and cross-references to other applications.

- (a)(1) A nonprovisional application may claim an invention disclosed in one or more prior filed conending nonprovisional applications or copending international applications designating the United States of America. In order for a nonprovisional application to claim the benefit of a prior filed copending nonprovisional application or copending international application designating the United States of America, each prior application must name as an inventor at least one inventor named in the later filed nonprovisional application and disclose the named inventor's invention claimed in at least one claim of the later filed nonprovisional application in the manner provided by the first paragraph of 35 U.S.C. 112. In addition, each prior application most her
- (i) An international application entitled to a filing date in accordance with PCT Article 11 and designating the United States of America; or
  - (ii) Complete as set forth in § 1.51(b); or

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- (iii) Entitled to a filing date as set forth in § 1.53(b) or § 1.53(d) and include the basic filing fee set forth in § 1.16; or
- (iv) Entitled to a filing date as set forth in § 1.53(b) and have paid therein the processing and retention fee set forth in § 1.21(1) within the time period set forth in § 1.53(f).
- (2) Except for a continued prosecution application filed under § 1.53(d), any nonprovisional application claiming the benefit of one or more prior filed copending nonprovisional applications or international applications designating the United States of America must contain a reference to each such prior application, identifying it by application number (consisting of the series code and serial number) or international application number and international filing date and indicating the relationship of the applications. Unless the reference required by this paragraph is included in an application data sheet (§ 176), the specification must contain or be amended to contain such reference in the first sentence following any title. The request for a continued prosecution application under § 1.53(d) is the specific reterence required by 35 U.S.C. 120 to the prior application. The identification of an application by application number under this section is the specific reference required by 35 U.S.C. 120 to every application assigned that application number. Cross-references to other related applications may be made when appropriate (see § 1.14(a)).
- (3) A maprovisional application other than for a design patent may claim in invention disclosed in one or more prior tidel coperating provisional applications. In order for a neuprovisional application to claim the benefit of one or more poor filed coperating provisional application, each prior provisional application must name as an inventor at least one inventor taineal at the later filed nonprovisional application and discloses the named inventor's invention claimed in at least one claim of the later filed nonprovisional application in the summer provided by the first puragraph of 55 U.S.C. 112. In addition, each prior provisional application must be entitled to a filing date as set forth in \$1.524.c, and are required finglish-language translation filed therein within the time period set forth in \$1.524.c, and three places of first in \$1.524.c, and three places of first in \$1.524.c. and three places first in \$1.524.c. and street places from the basic fifting lee set forth in \$1.524.c. and three places first in \$1.524.c. and \$1.534.c. and \$1.534.c.
- (4) Any nonprovisional application claiming the benefit of one or more prior filed copending provisional applications must contain a reference to each such prior provisional application, identifying it as a provisional application, and including the provisional application number (consisting of series code and serial number). Unless the reference required by this paragraph is included in an application data sheet (§ 170), the specification must contain or be amended to contain such reference in the first serticace following any title.

\*\*\*\*

Under certain conditions specified below, a Certificate of Correction can be used, with respect to 35 U.S.C. 120 and 119(e) priority, to correct:

- (A) the failure to make reference to a prior copending application pursuant to 37 CFR 1.78(a)(2) and (a)(4); or
- (B) an incorrect reference to a prior copending application pursuant to 37 CFR 1.78(a)(2) and (a)(4).

For all situations other than where priority is based upon 35 U.S.C. 365(c), the conditions are as follows:

- (A) for 35 U.S.C. 120 priority, all requirements set forth in 37 CFR 1.78(a)(1) must have been met in the application which became the patent to be corrected.
- (B) for 35 U.S.C. 119(e) priority, all requirements set forth in 37 CFR 1.78(a)(3) must have been met in the application which became the patent to be corrected; and
- (C) it must be clear from the record of the patent and the parent application(s) that priority is appropriate. See MPEP § 201.11 for requirements under 35 U.S.C. 119(c) and 120.

Where 35 U.S.C. 120 and 365(c) priority based on an international application is to be asserted or corrected in a patent via a Certificate of Correction, the following conditions must be satisfied:

- (A) all requirements set forth in 37 CFR 1.78(a)(1) must have been met in the application which became the patent to be corrected:
- (B) it must be clear from the record of the patent and the parent application(s) that priority is appropriate (see MPEP § 201.11); and
- (C) the patentee must submit with the request for the certificate copies of documentation showing designation of states and any other information needed to make it clear from the record that the 35 U.S.C. 120 priority is appropriate. See MPEP § 201.13(b) as to the requirements for 35 U.S.C. 120 priority based on an international application.

If all the above-stated conditions are satisfied, a Certificate of Correction can be used to amend the patent to make reference to a prior copending application, or to correct an incorrect reference to the prior copending application. Note In re-Schuturs, 218 USPQ 443 (Comm's Pat. 1983) which suggests that a Certificate of Correction is an appropriate remedy for correcting, in a patent, reference to a prior copending application. Also, note In re Lambrech, 202 USPQ

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620 (Comm'r Pat. 1976), citing *In re Van Esdonk*, 187 USPO 671 (Comm'r Pat. 1975).

If any of the above-stated conditions is not satisfied, the filing of a reissue application (see MPEP § 1401 - § 1460) would be appropriate to pursue the desired correction of the patent.

## B. For Applications Filed on or After November 29, 2000

For applications filed on or after November 29, 2000, the version of 37 CFR 1.78 reproduced below applies (note that amendments to 37 CFR 1.78 took effect on November 29, 2000, December 28, 2001, May 1, 2003, January 21, 2004, September 21, 2004, December 8, 2004, \* July 1, 2005>, and November 25, 2005<.

37 CFR 1.78. Claiming benefit of earlier filing date and cross-references to other applications.

(a)(1) A nonprovisional application or international application designating the United States of America may claim an invention disclosed in one or more prior-filed copending, nonprovisional applications or international applications designating the United States of America. In order for an application to claim the benefit of a prior-filed copending nonprovisional application or international application designating the United States of America, each prior-filed application must aim as an inventor at least one inventor amend in the later-filed application and disclose the named inventor's invention claimed in at least one claim of the later-filed application in the namer provided by the first paragraph of 35 U.S.C. 112. In addition, each prior-filed application must be:

 (i) An international application entitled to a filing date in accordance with PCT Article 11 and designating the United States of America; or

(ii) Entitled to a lifting date as set forth in § 1.53(b) or § 1.53(d) and have paid therein the basic filling fee set forth in § 1.16 within the pendency of the application.

(2)(i) Except for a continued prosecution application titled under 3 1 Styld, any nonprovisional application or international application designating the United States of America claiming the benefit of one or more prior-filled copending nonprovisional applications or international applications designating the United States of America must contain or be amended to contain a reference to each such prior-filled application, identifying it by application number (consisting of the sense code and serial number) or international application number and international filling date and indicating the relationship of the applications. Cross references to other related applications are be made when appropriate (see § 1.14).

(ii) This reference must be submitted during the pendency of the later-filed application. If the later-filed application is an application tiled under 35 U.S.C. 111(a), this reference must also be submitted within the later of four months from the section. Ifting date of the later-filed application or sixteen mouths from the filling date of the prior-filled application. If the later-filled application is a nonprovisional application which antered the national stage from an international application after compliance with 30 U.S.C. 371, this reference must also be submitted within the later of four mouths from the date on which the national stage commenced under 35 U.S.C. 371 (b) or (f) in the later-filled international application or sixteen mouths from the filing date of the prior-filled application. These time periods are not extendable. Except as provided in paragraph (a)(3) of this section, the failure to timely submit the reference required by 35 U.S.C. 120 and paragraph (a)(2)(1) of filins section is considered a waiver of any benefit under 35 U.S.C. 121, at 35(c) to such prior-filed application. The time periods in this paragraph do not apply if the later-filled application is:

(A) An application for a design patent,

(B) An application filed under 35 U.S.C. 111 (a) before November 29, 2000, or

(C) A nonprovisional application which entered the national stage after compliance with 35 U.S.C. 371 from an international application tiled under 35 U.S.C. 363 before November 29, 2000.

(iii) If the later-lited application is a nonprovisional application, the reference required by this paregroph must be included in an application data sheet (§ 1.76), or the specification must contain or be amended to contain such reference in the first sentence(s) Glowing the title.

(iv) The request for a continued prosecution application under § 1.53(d) is the specific reference required by 33 U.S.C. 120 to the prior-filed application. The identification of an application by application number under this section is the identification of every application assigned that application number necessary for a specific reference required by 35 U.S.C. 120 to every such application assigned that application number.

(3) If the reference required by 35 U.S.C. 120 and pengraph (α/2.) of this section is presented after the time period previoled by peragraph (α/2.) of this section, the claim under 35 U.S.C. 120, 121, or 365(c) for the benefit of a prior-filled copending nonprovisional application or international application designating the United States of America may be accepted if the reference identifying the prior-filled application by application number or international application number and international filling date was unmentionally deleted. A perittion to accept an unintertinionally deleted claim under 35 U.S.C. 120, 121, or 365(c) for the benefit of a prior-filled application number conformation.

(i) The reference required by 35 U.S.C. 120 and paragraph (a)(2) of this section to the prior-filed application, unless previously submitted;

(ii) The surcharge set forth in § 1.17(t), and

(iii) A statement that the entire delay between the date the claim was due under paragraph  $(a/2\chi ii)$  of this section and the date the claim was filed was manientonal. The Director may require additional information where there is a question whether the delay was unintentional.

(4) A nonprovisional application, other than for a design patent, or an international application designating the United States of America may claim an invention disclosed in one or

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more prior-filed provisional applications. In order for an application to claim the benefit of one or more prior-filed previsional applications, each prior-filed provisional application must name as an inventor at least one inventor named in the later-filed application and disclose the named inventor's invention claimed in at least one claim of the later-filed application in the manner provided by the first paragraph of 35 U.S. C. 112. In addition, each prior-filed provisional application must be entitled to a filing date as set forth in § 1.53(c), and the base filing fee set forth in § 1.154(d) must be paid within the time period set forth in

- (S)1) Any nonprovisional application or international application designating the United States of America claiming the benefit of one or more prior-tiled provisional applications must, contain or be amended to contain a reference to each such priorfilled provisional application, identifying it by the provisional application number (consisting of series code and serial number).
- (ii) This reference must be submitted during the nendency of the later-filed application. If the later-filed application is an application filed under 35 U.S.C. 111(a), this reference must also be submitted within the later of four months from the actual filing date of the later-filed application or sixteen months from the filing date of the prior-filed provisional application. If the laterfiled application is a nonprovisional application which entered the notional stage from an international application after compliance with 35 U.S.C. 371, this reference must also be submitted within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) in the later-filed international application or sixteen months from the filing date of the prior-filed provisional application. These time periods are not extendable. Except as provided in paragraph(a (6) of this section, the failure to timely subunt the reference is considered a waiver of any benefit under 35 U.S.C. 119(e) to such prior-filed provisional application. The time periods in this paragraph do not apply if the later-filed application is
- (A) An application filed under 35 U.S.C. 111(a) before November 29, 2000, or
- (B) A nonprovisional application which entered the national stage after compliance with 35 U.S.C. 371 from an international application filed under 33 U.S.C. 363 before November 29, 2000
- (iii) If the later-filed application is a nonprovisional application, the reference required by this paragraph must be included it an application data sheet (§ 1.76) or the specification must contain or be amended to contain such reference in the first sentence(s) following the title.
- (iv) If the prox-filed provisional application was filed in a language other than English and both an English-language translation of the prior-filled provisional application and a starement than the translation is accurate were not previously. Filed in the proof-filed provisional application, applicant will be notified and given a period of time within which to file, in the prior-filed provisional application, the translation and the statement. If the notice is mailed in a pending nonprovisional application, a timely reply to such a notice must include the filing in the nonprovisional application of either a confirmation that the translation and statement were filed in the provisional application, or an amaziment.

- or Supplemental Application Data Sheet withdrawing the benefit claim, or the nonprovisional application will be abandored. The translation and statement may be filed in the provisional application, even if the provisional application has become abandored.
- (6) If the reference required by 35 U.S.C. 119(g) and paragraph (a)(5) of this section is presented in a nonprovisional application after the time period provided by paragraph (a)(5) in of this section, the claim under 35 U.S.C. 119(g) for the benefit of a prior filed provisional application may be accepted during the pendency of the later-filed application if the reference identifying the prior-filed application by provisional application number was unministrationally delayed. A petition to accept an unintentionally delayed claim under 35 U.S.C. 119(g) for the benefit of a prior filed provisional application must be accompanied by:
- (i) The reference required by 35 U.S.C. 119(e) and paragraph (a)(5) of this section to the prior-filed provisional application, unless previously submitted;
  - (ii) The surcharge set forth in § 1.17(tg and
- (iii) A statement that the entire delay between the date the claim was due under peragraph (a\( \)\( \) \( \) \) ii) of this section and the date the claim was filed was unintentional. The Director my require additional information where there is a question whether the delay was mintentional.
- (h) Where two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application.
- (e) If an application or a patent under reexamination and at least one other application neumag different inventors are owned by the same person and contain conflicting claims, and there is no statement of record undertaing that the elasmed inventions were commonly owned or subject to an obligation of assignment to the same person at the time the later invention was made, the Office may require the assigned to state whether the claimed inventions were commonly owned or subject to an obligation of assignment to the same person at the time the later invention was made, and it not, indicate which manded inventor is the prior inventor. Even if the claimed inventions were commonly owned, or subject to an obligation of assignment to the same person, at the time the later invention was made, the conflicting claims may be rejected under the doctrine of double patenting in view of such commonly owned or assigned understours or relatest under reexamination.

Under no circumstances can a Certificate of Correction be employed to correct an applicant's mistake by adding or correcting a priority claim under 35 U.S.C. 119(e) for an application filed on or after November 29 2000

Section 4503 of the American Inventors Protection Act of 1999 (AIPA) amended 35 U.S.C. 119(e)(1) to state that:

No application shall be emitted to the benefit of an earlier filed provisional application under this subsection mless an amendment containing the specific reference to the earlier filed provisional application is submitted at such time during the pendency of the application as required by the Director. The Director may consider the failure to submit such an amendment within that time period as a waiver of any benefit under this subsection. The Director may establish procedures, including the payment of a surcharge, to accept an unintentionally delayed submission of an amendment under this section during the pendency of the unbleation.

A Certificate of Correction is NOT a valid mechanism for adding or correcting a priority claim under 35 U.S.C. 119(e) after a patent has been granted on an application filed on or after November 29, 2000.

Under certain conditions as specified below, however, a Certificate of Correction can still be used, with respect to 35 U.S.C. 120 priority, to correct:

- (A) the failure to make reference to a prior copending application pursuant to 37 CFR 1.78(a)(2).
- (B) an incorrect reference to a prior copending application pursuant to 37 CFR 1.78(a)(2).

Where priority is based upon 35 U.S.C. 120 to a national application, the following conditions must be satisfied:

- (A) all requirements set forth in 37 CFR 1.78(a)(1) must have been met in the application which became the patent to be corrected:
- (B) it must be clear from the record of the patent and the parent application(s) that priority is appropriate (see MPEP § 201.11); and
- (C) a grantable petition to accept an unintentionally delayed claim for the benefit of a prior application must be filed, including a surcharge as set forth in 37 CFR 1.17(t), as required by 37 CFR 1.78(a)(3).

Where 35 U.S.C. 120 and 365(c) priority based on an international application is to be asserted or corrected in a patent via a Certificate of Correction, the following conditions must be satisfied:

- (A) all requirements set forth in 37 CFR 1.78(a)(1) must have been met in the application which became the patent to be corrected:
- (B) it must be clear from the record of the patent and the parent application(s) that priority is appropriate (see MPEP § 201.11);
- (C) the patentee must submit together with the request for the certificate, copies of documentation showing designation of states and any other informa-

tion needed to make it clear from the record that the 35 U.S.C. 120 priority is appropriate (see MPEP § 201.13(b) as to the requirements for 35 U.S.C. 120 priority based on an international application; and

(D) a grantable petition to accept an unintentionally delayed claim for the benefit of a prior application must be filed, including a surcharge as set forth in 37 CFR 1.78(a)(3).

If all the above-stated conditions are satisfied, a Certificate of Correction can be used to amend the patent to make reference to a prior copending application, or to correct an incorrect reference to the prior copending application, for benefit claims under 35 U.S.C. 120 and 365(c.)

If any of the above-stated conditions is not satisfied, the filing of a reissue application (see MPEP § 1401 - § 1460) may be appropriate to pursue the desired correction of the patent for benefit claims under 35 U.S.C. 120 and 365(c).

## 1485 Handling of Request for Certificates of Correction [R-7]

A request for a Certificate of Correction should be addressed to:

Commissioner for Patents Office of Patent Publication ATTN: Certificate of Correction Branch P.O. Box 1450 Alexandria, VA 22313-1450

Requests for Certificates of Correction will be forwarded to the Certificate of Correction Branch of the Office of Patent Publication, where they will be listed in a permanent record book.

If the patent is involved in an interference, a Certificate of Correction under 37 CFR 1.324 will not be issued unless a corresponding motion under 37 CFR 41.121(a)(2) or 41.121(a)(3) has been granted by the administrative patent judge. Otherwise, determination as to whether an error has been made, the responsibility for the error, if any, and whether the error is of such a nature as to justify the issuance of a Certificate of Correction will be made by the Certificate of Correction Branch. If a report is necessary in making such determination, the case will be forwarded to the appropriate group with a request that the report be furnished. If no certificate is to issue, the party making

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